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PRESENTATION

Operator

Good morning. And welcome to Moderna's Fourth Quarter and Full Year 2019 Conference Call. (Operator Instructions) Please be advised that the call is being recorded. At this time, I'd 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. On today's call, we will discuss Moderna's fourth quarter and full year 2019 business update 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 Chief Executive Officer; Tal Zaks, our Chief Medical Officer; Stephen Hoge, our President; and Lorence Kim, our Chief Financial Officer.

Before we begin, I would like to remind everyone 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.

I will now turn the call over to Stéphane.

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

Thank you, Lavina. And good morning, everyone.

As you know, we believe mRNA has the potential to be a new class of medicines with the opportunity to address many unmet medical needs. Given the unknowns of working with a new technology, we have been laser-focused on managing risk: technology risk, biology risk, execution risk and financing risk.

2019 was an important inflection year for Moderna. We reported clinically validating data from key programs in 2 of our modalities, prophylactic vaccines on the left and systemic secreted and cell surface therapeutics on the right, data that we believe fundamentally changed the risk profile of each of these 2 modalities that we now call core modalities.

As a result, our strategy is to double down in these 2 core modalities with many important medicines. We have already announced 5 new development candidates in these core modalities 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 therapeutic modalities.

While we've doubled down in core modalities, we are still more than ever interested in understanding the potential of our mRNA technology in our exploratory modalities: cancer vaccines, intratumoral immuno-oncology, localized regenerative therapeutics and systemic intracellular therapeutics. So when we think about this, we have 2 distinct businesses. This is a significant point in our strategy. Core modalities, where we want to scale and invest; exploratory modalities where we are waiting for clinical data to decide on the path forwards.

So stepping back, I would like to share with you the progression of the company toward a new class of medicines.

In the early days of Moderna's history, our goal was to enter the clinic safely. We spent years investing and developing mRNA science, formulation delivery and manufacturing. 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 technologies 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 core modalities, infectious disease prophylactic vaccines and systemic secreted and cell surface therapeutics.

We're entering the new phase of the company's development. Our goal for this next phase of our history is to find multiple BLAs while continuing to explore on our clinical programs in our 4 exploratory modalities, with support to invest aggressively in our science, including inventing new modalities such as our ongoing collaboration with Vertex. We were fortunate to be able to close the financing earlier this year so we can maximize the potential to create value and manage risk. Once we file multiple BLAs, our goal will be to scale the company and commercialize a large portfolio of mRNA medicines.

Now Tal will take you through our prophylactic vaccine programs.

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. In over 1,000 healthy volunteers and 6 positive Phase I data sets to date, we have observed a safety profile consistent with the safety of marketed vaccines and the ability to elicit an immune response in the form of neutralizing antibodies.

Updates for the ongoing programs are shown on this slide. The CMV Phase II dose confirmation study is enrolling well. We completed the second dose cohort and are close to completing the third one. We now expect data readout to come in the third quarter of this year.

Our hMPV/PIV3 combination respiratory vaccine has started the age de-escalation study, and Merck is on track with their RSV program in adults. Zika is also going well as 3 of the 4 dose cohorts have completed enrollment. Our 3 new development candidates announced recently are vaccines

against pediatric RSV, mRNA-1345, Epstein-Barr virus, or EBV, mRNA-1189, and our vaccine against the novel 2019 coronavirus, mRNa-1273. Stephen will take you through each of these candidates in a minute.

CMV is an unmet need as there aren't any approved vaccines, and the burden of disease from CMV infection is significant. Of the 25,000 newborns in the U.S. affected each year, 20% will have permanent neuro developmental disabilities. And the spectrum of sequelae range from hearing loss, vision loss, microcephaly and even mortality in 10% to 30% of the severely affected infants. We believe our gB and pentamer vaccine has the potential to prevent CMV infection and help thousands of newborns avoid these sequelae.

On Slide 16, I'll review the most recent data from our CMV program. In January of this year, we shared the 7-month interim data. The safety has been generally well-tolerated, and we've not seen any related serious adverse events. Immunogenicity data continues to confirm earlier interim data from the trial and continues to exceed our expectations. Specifically, we continue to see higher neutralizing antibody titers in seronegatives and seropositives in both epithelial and fibroblast assays.

If you look at those who have never had CMV, the seronegative group, after the third vaccination, they had neutralizing titers against epithelial cells that were more than tenfold higher than the levels seen in seropositives at baseline. We also saw a nice increase in titers against the fibroblasts. Even in seropositives, people who have been infected, our vaccine is able to boost them twenty to fortyfold higher above baseline level after the third vaccination, and we see early evidence of durability out to 12 months. These data are what's behind our optimism and belief that we can take this vaccine all the way through to prevent infections in newborns.

As mentioned earlier, our Phase II dose confirmation study is enrolling well and is currently enrolling the last dose cohort. We now expect data from the first interim analysis in the third quarter of this year. Preparation for the Phase III trial that we anticipate will include less than 8,000 participants, including women of childbearing age, are underway. An early estimate of the cost of this trial is in the range of $200 million to $250 million.

Now as an opportunity for us, CMV is clearly a blockbuster opportunity. We estimate annual peak sales for a CMV vaccine to be in the range of $2 billion to $5 billion, in line with the estimates of others in the field.

Assuming an average selling price like GARDASIL, a relevant comparator here, we estimate gross margins of about 90% and EBIT margins of approximately 50%. We're excited about the progress towards this opportunity, supported by the fact that just 1 of the antigens in our vaccine, the gB, when encoded for in a traditional recombinant technology in the past, had already shown a 50% efficacy, which was demonstrated by Sanofi several years ago. We believe that targeting both the pentamer and gB antigens, as our CMV vaccine does, will be additive to the vaccine's efficacy.

As a reminder, our CMV vaccine, mRNA-1647, is wholly owned by us.

Let me transition it to Stephen to talk about our new development candidates.

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Tal.

I want to start by introducing 3 development candidates in our vaccine -- prophylactic vaccines modality that we've recently announced earlier this month.

The first is against Epstein-Barr virus. And just want to pause for a moment and give you an overview of the disease. So Epstein-Barr virus is a member of the herpes family that includes CMV and is spread through bodily fluids, mostly in the young children and adolescents. EBV is a major cause of a wide range of diseases, but is the leading cause of infectious mononucleosis in the United States, accounting for almost 1 million cases annually. Infectious mononucleosis can debilitate patients for weeks to months, and in rare cases, can lead to hospitalization and even splenic

rupture. EBV infection is also associated with a range of other disorders, including lymphoproliferative disorders, cancers and autoimmune diseases. I mean, for instance, it is associated with a significant increase in risk of multiple sclerosis. There are currently no approved vaccines for EBV.

So our vaccine candidate, mRNA-1189, is designed to provide broad protection against EBV infection and infectious mononucleosis. EBV has a number of surface proteins on its envelope, including gp350, a trimeric complex of gp42, gH and gL, a dimeric complex and also gB. All of those antigens are important for infecting a range of different cell types, but particularly, B cells and epithelial cells.

Now vaccination against only one of those antigens, gp350, which provides only partial B cell protection, reduced the rate of infection in a prior study by up to 7 -- reduced the rate of infectious mononucleosis in a prior study by up to 78%, but it did not prevent the rate of infection. We believe that the combination of multiple antigens, gp350, plus antigens for -- or gp42/gH/gL and gB will provide an opportunity for broader protection both at B cells and epithelial cells, very analogous to our approach with the cytomegalovirus vaccine.

Now we estimate that the opportunity is quite substantial. Worldwide direct cost of EBV-linked infectious mononucleosis reached almost $500 million annually, and the indirect costs could exceed $1 billion. But prevention of infection, EBV infection, in addition to the prevention of infectious mononucleosis, could represent a much more significant upside because of the associated increased risk in cancers and multiple sclerosis. These will represent a long-term potential but are not currently a focus of our current clinical development plan.

Heading now to our second recently announced program, which is for respiratory syncytial virus in the pediatric population, I want to pause and provide a little bit of an overview of the disease again.

RSV is the leading cause of unaddressed severe lower respiratory tract disease and hospitalization in infants and young children worldwide. It's a major cause of hospitalization in this country, accounting for up to 86,000 hospitalizations a year and over 2 million medically attended RSV infections in children under the age of 5. Globally, the burden of disease is even more substantial, with over 30 million episodes of acute lower respiratory tract infection annually. And we estimate that the direct costs associated with pediatric RSV disease in the children under the age of 5 exceed $2 billion annually.

So our target population for this vaccine is the young, under the age of 5 children for respiratory syncytial virus. There is currently no approved RSV vaccine in that population.

Our candidate, mRNA-1345, encodes for a stabilized prefusion F glycoprotein, analogous to our other efforts in RSV vaccines. mRNA-1345 will use the same proprietary lipid nanoparticle as our hMPV/PIV3 vaccine, mRNA-1653 as well as the CMV vaccine that Tal just described. And we believe that neutralizing antibodies elicited by 1345 will lead to a reduction of medically attended RSV disease in the very young.

And while that's exciting, we actually intend to combine 1345 with mRNA-1653 to create a combination pediatric vaccine -- respiratory vaccine, which will address over 3 million medically attended lower respiratory track and upper respiratory track infections annually in the U.S. alone. That combination of mRNA-1345 and 1653 would represent a significant opportunity to address unmet need.

The current plan is to develop 1345 and 1653 independently in the near-term through their initial clinical studies, but we would combine them prior to registrational studies and ultimately advance a joint product.

Now the third vaccine that we announced earlier this month is our mRNA vaccine against the SARS CoV-2 virus, recently named the novel coronavirus that's associated with COVID-19 disease. mRNA-1273 is an mRNA vaccine that encodes for a prefusion stabilized form of the Spike protein of that novel coronavirus that had been selected by Moderna in collaboration with the National Institute of Allergy and Infectious Diseases, the vaccine -- and the Vaccine Research Center, which are both part of the NIH.

The first clinical batch for our Phase I, including finishing and filling of vials, was completed on February 7. And earlier this week, that batch was shipped to the NIH for the Phase I study. And NIAID will conduct that Phase I study under their own IND in the near term.

Now pivoting to our second core modality. Earlier this year, we did announce 2 additional programs in the autoimmune therapeutic area in our systemic secreted and cell surface therapeutics. And as we described them at JPMorgan, I won't go into great detail, but to briefly recap them here.

IL-2 -- our IL-2 program, mRNA-6231, encodes for a long-acting tolerizing IL-2. As you can see in the lower right-hand corner on this page, we've demonstrated that in nonhuman primates at a single subcutaneous injection of mRNA-6231 can lead to a substantial increase in T reg cells without increasing activated cells. That provides an opportunity to reestablish immune balance across -- that might be relevant for a wide range of autoimmune diseases. There are a number of different recombinant IL-2 based therapeutics that have shown potential, and we will be advancing this program into the clinic in the near term.

Second program we announced earlier this year was PD-L1, mRNA-6981. It's an mRNA-encoded PD-L1 to send a tolerizing signal to immune cells. In this case, we are expressing PD-L1 on the myeloid antigen-presenting cell. And the purpose of that is to drive a tolerogenic phenotype, a reestablishment of immune homeostasis in effector cells, including T cells and B cells.

mRNA-6981 will be an IV infusion, using the same LNP as our mRNA-encoded antibody, mRNA-1944, that had previously been described.

And in preclinical disease models across a wide range of autoimmune conditions, we've demonstrated ability to modify the disease as you can see on the lower right-hand corner, one example, which is collagen-induced arthritis. The first indication in which we're going to be bringing the PD-L1 program forward is in autoimmune hepatitis, a disease we see a compelling unmet need.

Now with that, I'll turn it back over to Tal to talk about our other work in exploratory modalities.

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

Thank you, Stephen.

Let me just briefly review these modalities that we consider exploratory, but obviously make up a significant part of what we do in clinical research and give you a sense where we are in the prosecution of these programs.

Starting with the cancer vaccines. Our personalized cancer vaccine, mRNA-4157, is in a randomized Phase II trial for the treatment of adjuvant melanoma, in the combination of PCV with KEYTRUDA against KEYTRUDA alone, and it's recruiting well.

KRAS vaccine, mRNA-5671, is an ongoing Phase I study, and this one is led by Merck and it has a monotherapy as well as a combination with KEYTRUDA arm.

Our intratumor immuno-oncology therapeutics, we have 3 programs in this modality. All of them are in combination with PD-1 inhibitors. Dosing of patients is ongoing, and I look forward to the future to being able to demonstrate whether the ability to influence the immune system in this manner will be helpful to these patients.

On the regenerative therapeutics modality, AstraZeneca is conducting a Phase IIa in patients with our mRNA that encodes for vascular endothelial growth factor. And that's in patients that are undergoing CABG, coronary artery bypass grafting. That study continues to enroll.

In the systemic intracellular therapeutics, we have 2 INDs open now in both MMA and PA, methylmalonic acidemia and propionic acidemia. I'm pleased to announce that the first patient in MMA has enrolled in this trial. They're in the observation period right now. This trial is now open at 7 institutions in the United States, and we're continuing to look for additional patients to enroll while we follow this first patient closely.

With that, let me turn it over to Lorence to describe the rest of our pipeline and where we go from here.

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

Thank you, Tal.

So on Slide 29, you see a graphic that represents our whole development pipeline as it stands today. First and foremost, we're focused on the advancement and execution around this development pipeline.

You heard 3 significant things from us today around the CMV vaccine, where the Phase III preparation is very much underway. You heard the Phase II enrollment for that CMV vaccine is ahead of schedule. And importantly, in Phase I, MMA has enrolled its first subject. So we're really focused on executing across the entire breadth of the pipeline.

And then the other key thing you heard today is that the preclinical programs continue to grow. And you will have heard that we announced in the first 2 months of the year 5 new development candidates. This is indicative of the productivity that we expect out of the research platform.

What this leads to on the next slide, it's a robust list of clinical data and next steps across the pipeline. If you scan the page, you'll see a lot of readouts coming in the near term. We've guided for the CMV readout, the Phase II data with a 3-month interim analysis in the third quarter of this year and a Phase III start in 2021.

And with the rest of the vaccines, you'll see a number of additional Phase I readouts that we would expect to occur as well as advancement of these newly nominated development candidates toward the clinic.

If you look at the next category of systemic secreted therapeutics, our antibody against Chikungunya will continue to progress through further development of a dose cohort and we'll continue to advance preclinical work towards IND filings.

And you just heard from Tal that the rest of our programs will be progressively moving forward here towards clinical data.

On Slide 31 and today's press release, we reported our fourth quarter and full year 2019 financial results. Please note, these results are unaudited as of this call. We'll be filing audited financials shortly with the 10-K.

We ended 2019 with cash, cash equivalents and investments of $1.26 billion. This compares to $1.69 billion at the end of 2018. Net cash used in operating activities was $459 million for 2019 compared to $331 million in 2018. And cash used for purchases of property and equipment was $32 million for 2019, a significant drop versus $106 million in 2018. We placed our Norwood Moderna Technology Center manufacturing facility in service in mid-2018.

Revenue for Q4 2019 was $14 million compared to $35 million for Q4 2018. And for the full year, revenue was $60 million compared to $135 million in 2018.

Recall that in January of 2019, we adopted the mandated revenue recognition standard, ASC 606, using a modified retrospective transition method applied to those contracts which weren't completed as of January 1, 2019. And so the decreases in revenue are largely attributable to the adoption of this new revenue standard, together with the completion of the initial 4-year research period under the 2016 Merck agreement.

Total revenue under the previous revenue recognition standard would have been $15 million for Q4 2019 and $95 million for the full year 2019.

R&D expenses for Q4 2019 were $119 million compared to $150 million for Q4 2018. And for the full year 2019, R&D dollars were $496 million compared to $454 million in 2018. The decrease in Q4 was mainly due to a decrease in our in-licensing payments to Cellscript and its affiliates and a reduction of our lab supplies and materials. The increase for the full year 2019 was mainly driven by an increase in personnel-related costs, including stock-based comp, driven by an increase in the number of employees as well as higher clinical trial and manufacturing costs.

G&A expenses for Q4 were $26 million compared to $38 million in Q4 2018. And for the full year, G&A expenses were $110 million compared to $94 million in 2018. The decrease in Q4 was primarily driven by a decrease in stock-based comp, mainly attributable to certain performance-based

equity awards with vesting or commencement contingent on the IPO in 2018. And the increase for the full year 2019 was mainly due to the additional costs of operating as a publicly traded company, including the increases in insurance, consulting and outside services and facility costs.

On the next slide, we show the progression of selected cash flow line items, namely our net cash used in operating activities and our purchases of property and equipment. The table shows you our GAAP results by period with a total operating cash flow plus PP&E.

I'd point you primarily to the bar chart, which shows the quarter-by-quarter progression of this metric. And you'll see that our cash use shows a steady reduction through 2019. I would note that Q1 contained the impact of the last of the 3 licensing milestone payments we owed Cellscript, which is $22 million.

I don't expect this downward trend to continue to decline quarterly in 2020. But for the full year, you can see how we ended up overall flat versus 2019 when we thought about expectations, even with the advancement of our pipeline through the clinic. And so the result -- we'll reiterate our guidance for 2020, which is that net cash used in operating activities and purchases of PP&E will total between $490 million and $510 million.

That approximate $500 million of cash investment into our business is put into context on the next slide versus the cash that's available to us for investment. Here, you see our year-end cash balance of $1.26 billion. And on top of that is the net proceeds of approximately $550 million from our equity offering, which includes the exercise of the underwriter's option to purchase additional shares that we anticipate to close later today.

And then as we've mentioned before, we have approximately $185 million in potential future grants available to us as well. And so these amounts sum up to $2 billion in available cash, which we expect to invest in our business. And that represents a significant cash runway of multiple years.

I'll now hand it back to Stéphane to close.

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

Thank you, Lorence and Stephen.

On Slide 35, you can see an update on Moderna's file. Our company has never been stronger. Our pipeline. Preparing for CMV Phase III, 4 medicines in or preparing for Phase II, 11 Phase I trial is ongoing and 10 positive clinical readouts. Our programs in development. 7 vaccines, where there are no approved vaccines on the market. Most of these vaccine candidates have multibillion-dollar annual peak sales opportunities.

As I shared in our 2019 shareholder letter, we believe our innovative vaccines are going to be very large business for Moderna, with long-term, long-term annuity life opportunity and a high EBIT margin, 5 immuno-oncology drugs in the clinic, 5 rare disease programs with our first Phase I started for MMA, 2 autoimmune diseases program.

The foundations of Moderna have never been stronger. Our clinical experience is now more than 1,700 healthy volunteers and patients. The team is strong with more than 800 employees who care deeply about our mission and are proud of and energized by our progress.

I would like to thank our entire team. I would like to extend a special thank you to those who made the coronavirus vaccine from sequence to shipping to NIH for Phase I dosing in only 42 days. And we are proud to be included with those many companies working on a possible response to this continuing global health emergency.

Norwood, this a fully digital, fully integrated facility that enables the execution of our pipeline, all the way from raw materials to finished vials ready to ship to the clinic. We have great partners with AZ, Merck, Vertex, Defense or DARPA, BARDA, CEPI and the Gates Foundation. As we said on November quarterly call, we are working on expanding that network of partners as we speak.

With the financing, our grant capital and our cash balance, we're in a fortunate position to invest up to $2 billion towards building the leading mRNA company. We are thankful to our investors for their trust and partnership as we build this unique company.

For 2020, our priorities are very clear. Priority #1, execute on our development pipeline with a special focus on CMV Phase III start. Priority #2 is creating new development candidates in the 2 core modalities. We're already at 5 in the last 2 months only. And priority #3 is to develop new development candidate in new modalities. Stay tuned here.

As a reminder, these are the events we are hosting for analysts and investors in 2020. Our first Manufacturing and Digital Day is next week on Wednesday at our Norwood facility in Massachusetts. A webcast will be available on our website. Juan Andres and his team will share many new insights, including how the team delivered coronavirus vaccine in 42 days from sequence to shipping. Marcello Damiani and his team will share the progress since opening Norwood in July 2018 on the digital front, including use cases of artificial intelligence and machine learning. We hope to host many of you for first Vaccine Day in New York City on April 14 for a deep dive into our mRNA vaccine modality. We will discuss, among other things, clinical data, business model, how we think about value creation, capital allocation and probability of success of our mRNA vaccines.

In June, we look forward to hosting our first Science Day to be able to share with you the many progress the team has made on mRNA science and delivery since Science Day 2019.

In September, we'd also like to welcome you for our fourth R&D Day, where, as usual, in New York, we will review in detail clinical data.

As I shared in my introduction, Moderna is entering a new phase of its development as a company. Our goals are clear. One, file multiple BLAs and launch multiple medicines, which we own commercially; and two, continue to explore modalities in the clinic and invest in science.

We have 2 core modalities and are now laser-focused on filing multiple BLAs and then scaling Moderna to maximize our impact on patients. We are continuing to realize our vision. We have got 12 innovative medicines currently in the clinic.

We are only getting started. mRNA is an information molecule. Because of that, we believe that the probability of technical success for our medicines from the lab to approval will be materially higher than traditional medicines.

Speed. Our track record speaks louder than words. Coronavirus from sequence to shipping clinical-grade product, 42 days. Evidence of greater capital efficiency relative to traditional recombinant technology is becoming apparent. We can do new disease like EBV and pediatric RSV without additional capital invested.

I have never been more optimistic about Moderna's future and potential since joining as employee #2 in 2011. I believe mRNA is going to be a new class of medicines, and I believe Moderna is the leading company in that field.

With $2 billion to invest, a great team, our science, our IP and the manufacturing site at Norwood, we will work to accelerate our leadership in the months and quarters to come. We are excited by the opportunity to bring forward a new class of medicines for patients.

I'd like to thank the great team of Moderna employees working hard every day and sometimes every weekend to make this vision a reality. I would like to thank the many people who participate in our clinical studies, including patients, healthy volunteers and physicians. I would also like to recognize all our commercial partners, our commercial partners who work with us and share our vision to deliver transformative medicines for patients.

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

QUESTIONS AND ANSWERS

Operator

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

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

I guess 2 for me. So one, on coronavirus, and I think this is just so people understand. Could you just broadly comment? It sounded like NIH needs to file an IND and then they would obviously start the clinical study. What is your involvement at this point? And are you taking any steps related to ramping manufacturing or any other steps related to this? And then secondly, maybe just on CM -- well, actually, on MMA. Can you just talk about how enrollment is going for additional patients? What sort of led you to be able to get that first patient in? And if you see promise in terms of being able to rapidly enroll additional patients.

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

Thanks, Matthew. This is Tal. Let me take both of these questions. As it relates to coronavirus, our part here was to manufacture and ship it. I think the trial now will be run by the NIH, and I defer to them to provide updates when they will. You asked about scale-up. I think we're looking at everything that it would take and how to actually get it done. But we'll update everybody once we have a clear picture of that. Obviously, this is a rapidly changing environment.

On M&A enrollment, so right now, we've got one patient enrolled. We do not yet have a second and third, but we're actively working with sites to find them. The age barrier, I think, continues to be a difficult one. We only have to find the first 3, so -- and then we can go down in age. So I am confident that we will eventually, but I continue to have a dialogue with the agency on trying to reduce that need so that enrollment can be unhooked from that and we can get into the age population where we believe the greatest unmet need and potential for benefit is. So I'll update everybody as soon as we have progress in that field.

Operator

Our next question is from Ted Tenthoff of Piper Sandler.

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

Great. And just following up on Matt's question first. What -- maybe you can just remind us again so that everybody understands it because I've getting a lot of questions on this. What is the process for licensure of a biothreat or pandemic vaccine such as coronavirus? And then with respect to CMV, again, great progress just across the board here. Ultimately, what do you see as sort of the vaccination paradigm or timing of vaccinations for women of childbearing age?

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

Thanks, Ted. It's Tal. Let me take that. I think what does it take to get licensure is an evolving field. I mean the pathways to licensure are well-understood, and they encompass everything from finding surrogates of protection to demonstrating efficacy. What is it going to take here? I don't think anybody knows. I think all options are currently open, but it's a rapidly evolving field. And you can imagine that there actually is not yet a surrogate of protection because this is a very new virus, and people are still working to develop those assays and models. I would give NIH a lot of credit for being at the forefront of that effort, and we're closely collaborating with them on these efforts.

As it relates to the vaccination paradigm for CMV, I think the starting point here is clearly going to be in women of childbearing age. That's where you would anticipate the greatest benefit. And I think the next phase is going to be to get into a GARDASIL-like population of adolescents because, obviously, you want to start protection as early as possible, given that's what -- the disease we're trying to prevent here is obviously going to be in infants born to women. So we're going to try and get down to that age group as we develop this vaccine.

Operator

Our next question is from Salveen Richter of Goldman Sachs.

Ross Howard Weinreb - *Goldman Sachs Group Inc., Research Division - Research Analyst*

It's Ross on for Salveen. Just a few here from me. So just quickly on coronavirus. What's the potential monetary opportunity here? Do you guys have any details around agreements with the NIH about funding to you guys? So just thinking about the monetary opportunity there to Moderna. And then on the Chikungunya antibody program, how much follow-up time exists since like the initial patient was first dosed and then since he was -- since he received a second dose? And are you guys seeing any signs of like innate immune response? And then I have a follow-up.

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

Good. So it's Stéphane. I'm going to start with the first one. On corona, our only focus as a team is public health. People are sick all over the planet. People are dying. But this is our only focus, is to get a vaccine as fast as we can safely, partnering with the right people to get it done.

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

Let me answer. If I understood correctly your question on the Chikungunya monoclonal antibody. These data are emerging. We're giving you an execution update on to-- in terms of where we are. Once I have a full sense of the data set there, I'll of course update everybody.

Ross Howard Weinreb - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Great. And then just lastly, so outside of the Phase II CMV update in 3Q, what programs are you expecting to have data this year?

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

We -- as you know, we don't guide to a specific timing on various milestones. I'd refer back to the slide which had the rich catalyst calendar and clinical data calendar that we referred to. That list of events that included data readouts as well as advancement of programs is -- it's a list that comprises all the next steps. Some of those have advanced fairly far along. For instance, I would note that the Phase I vaccine studies for RSV and Zika have been running since last year. And other instances, you'll recall that, as you pointed out, the Chikungunya antibody program is -- it's a relatively small study in healthy volunteers. But again, we're focused on advancing all these programs as rapidly as we can towards data.

Operator

Next question is from Geoff Meacham of Bank of America.

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

This is Alec on for Geoff. Two questions from me. My first is on your PCV program, and I guess, the KRAS vaccine as well, have you guys seen any updated data from these studies, including the ongoing Phase I for the PCV since ASCO? Just trying to get a sense of why this modality hasn't made the cut for your core franchises given it's one of the more advanced in terms of clinical development. And then I've got one more.

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

Thanks, Alec. It's Tal. Look, on the planned cancer vaccine. It's a Phase I, so data continues to come in. Once we have a full cogent data set there, we will be disclosing it. The question of why we don't consider this a core, I think, for us, core is one that we have gotten the requisite pharmacology to believe it will translate into a clinical benefit. And I think that's true both for the vaccines, clearly. And it's also true for the secreted and the surface protein expression because the Chikungunya monoclonal antibody actually reached what would otherwise be therapeutic levels of a protein. So that's why it's core. I think in oncology, until you actually show that you're -- the pharmacology that you're describing, in this case, immunology, and T cell immunology, until you actually demonstrate that, that translates into a clinical benefit for patients, it's hard for me to call it core.

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

Got it. That's very helpful. And then secondly, do you have any updates on the CF partnership with Vertex? We've seen Vertex partner with some other gene therapy approaches from CRISPR Therapeutics, Semma and others. So any color you can give on this partnership would be great.

Stephen Hoge - *Moderna, Inc. - President*

Yes. We don't generally comment on research. So we continue to work with Vertex. We're pleased to be working with them in the CFTR space, but we don't have any updates at this time.

Operator

Our next question is from Cory Kasimov from JPMorgan.

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

Two of them for you. First is another one on coronavirus, just thinking a little bit further out. Just curious, what kind of manufacturing capacity you anticipate having, say, looking out to 2021 even? Should you need to manufacture mRNA-1273 for coronavirus? And then secondly, for the CMV program, I mean, if you could just kind of broadly talk about what a win would look like in that interim update for the Phase II we'll get in 3Q? Is this more or less kind of just looking to replicate the Phase I results on a larger group of patients? Or are there nuances we should be thinking about?

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

So Cory, it's Stéphane. So I'll take the first one on manufacturing capacity. I think the punchline is just too early to know precisely. Plus, we don't know the dose, when fill, finish with Norwood CMO capacity -- potentially new sites. So just way too early to comment on that. But we are working hard to get as much as we can.

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

Cory, It's Tal. Let me answer your question on CMV Phase II. So I think in a nutshell, the goal here is, as you say, to replicate what we saw in the Phase I. But I'd like to be able to do that, of course, in a larger data set, so that our confidence in picking the right dose for Phase III is there. And that has to do both with replicating the nice immunogenicity that we've seen, but being able to kind of plant a clear flag on what we expect in terms of the safety and tolerability profile that would enable us to go into a Phase III trial.

Operator

Our next one is from Hartaj Singh of Oppenheimer & Company.

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

I have just a question on CMV. With the Phase II results coming up in the third quarter and then the Phase III getting going, could you talk a little bit about how you could speed it to market? I know that's -- a lot will be dependent on the Phase II results, but can you give us some sort of a kind of a confidence of more or less to when you think the Phase III could read out and by which time it could be on the market, 2024, '25, '26? And then just a follow-on to that, which is that you've quoted the CMV opportunity as being $2 billion to $5 billion, which seems to make a lot of sense because as you get to broader and broader immunity. Can you just broadly walk us through what kind of patient populations would you want to sort of have the vaccine broaden into to get to that higher point of that range?

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

Hartaj, this is Tal. Let me start by answering the first question. So look, the time line for CMV, roughly speaking, once we get in, we anticipate fairly aggressively to be able to complete enrollment within 18 months. I anticipate the duration of the trial to be 2 years. Now that still needs, of course, vetting with regulatory authorities. So I want to make sure I caveat that appropriately. Once that we have 2 years on everybody on study, then it's a matter of analyzing, looking at the results and filing, and that's where I think the time lines are pretty well understood for what's achievable in our industry. So you can do the math from there.

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

Yes. And Stéphane, I'll take the second one on CMV, what it will take to get to $5 billion type of number. I think a few things. The first one is, as we explained at the R&D Day in September, it will take definitely an indication approval in women in childbearing age, which, as you know, is our first one; then to get into adolescent approval, like the HPV GARDASIL; and third is to get to pediatric.

As we shared, humans are the reservoir for CMV. We believe it's a very important public health opportunity here to vaccinate newborns in the pediatric setting. That has been done, as you know, successfully with Rubella, to eradicate the virus, and to make sure that humans don't get infected by these virus, which has a lot of long-term negative impact on health, both at the population as well as for individuals and their own immune system and their own health. Another dimension, of course, is competitive landscape. Are we going to be the only one on the market for next 10 years or are we going to be with 1 competitor, or 2 competitor or 5 competitors. I can come back on that if you adjust it moving further. And then it's population growth. There's a lot of emerging markets that are not only growing in size in our population growth, but also in term of dollar invested per inhabitant. If you think about the 5-year, 10-year, 15-year time frame. That will impact the model that we have for getting to around $5 billion in our annual peak sales.

Operator

Our next question is from Yasmeen Rahimi of Roth Capital Partner.

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

Thank you for the tremendous progress that you're making quarter-over-quarter. A few questions for you all related on CMV. The first one is, can you give us a little bit more color on how we think about how current the numbers are in regards to infection rates? If there are differences between U.S. and Europe. How current they are as it guides you sort of for powering assumptions in your Phase III? And then a second question that we often get is, as you're in a phenomenal part of being able to scale up, and we're going to learn more in manufacturing on March 4. Can you enlighten us what are aspects that are unique when you're scaling up an mRNA therapeutic versus other RNA modalities? Just so we have a little bit of color, and nuances that you are looking here.

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

All right. It's me. It's Tal. Let me take your first question. It's a great question and it's one that obviously keeps me up at night. I think the literature is out there in terms of incidence rates and infections. But it's also clear from that literature that there's a high level of variability. And it's not just on a continental level, U.S. versus Europe, but it's actually local geographies, socioeconomic status, a lot of things that play into that. So how are we thinking about it in terms of designing the trial, which is, obviously, I think where your question is going to. I think the goal here is to design both a large trial and a broad enough trial in terms of sites and populations. So that on average, we are able to hit the incidence rate that people have described. And I'm pretty confident in the ballpark of where we are powering the study to be able to reach it.

And finally, I would note that in a trial of this type, you have the ability to actually, on an ongoing basis, monitor the incidents in real time. So that the only risk you're really taking, if you're missing it, is you follow subjects for longer and you catch up the cases. So it'll -- ultimately, the trial size will come down to the number of cases. And that's one that you can monitor in almost real time.

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

So Yasmeen, it's Stéphane. On the manufacturing process and why mRNA is such a powerful molecule. I think a few things. I mean the first thing is it's a liquid-based process to make mRNA, which is cell-free so that drives to a very small reactors compared to other technologies, especially if you compare to recombinant it's the most staggering changes, can too for given our -- just the size of our reactors, which, of course, has a big impact on your CapEx, including all your purification technologies because you just have less liters to go through the (inaudible). So everything is much, much cheaper across the board.

As we talked in the past, because mRNA is an information molecule, it is the same process for Zika, or for CMV, or for coronavirus. So drives incredible flexibility and the incredible time to the clinic, because do not have to invent the process for every vaccine or every molecule, as the team has shown in the last few weeks with coronavirus.

If we have had like traditional technologies to invent a new process just for corona, we'd still be working at it as we speak. And we most probably not even have started to make the product. In our case, we're able to just do a tiny bit of [optimization] for the very large molecule that this mRNA is and then go right into production. Thanks to the -- this aspect of a platform that we have.

And definitely it is time which is -- the cycle time to make mRNA is days, not weeks. And so when you think about that, you can use an asset. I mean once you make one lot, you can basically change the disposable equipment and use the same room or the same team to make another product. And so if you can deliver few days to make mRNA versus a few weeks to make a recombinant before you're going to go into fill, finish, that's a massive use of your capital infrastructure in term of just CapEx turnover.

Operator

(Operator Instructions) And next one is from Alan Carr of Needham.

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

And a couple of them. One of them is can you clarify between your exploratory and your core modalities? Does this mean that you don't plan to add any more new programs to your exploratory until they become core? And then also around RSV, 1345 versus 1172. How are they different? And how does this fall outside of the agreement that you already have with Merck around RSV? And the last thing is can you go over the -- your overall manufacturing capacity at the Norwood facility right now across all programs, the total capacity? And without regard to coronavirus, what were your -- what are your long-term plans in terms of your needs for capacity in terms of adding manufacturing capacity in the long term as you go commercial?

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

Good. Thanks for those 3 questions. So let me take the first one on exploratory and core. So yes, if you go back to the strategy, we started with 6 modalities in the clinic to say we cannot manage the unknown, unknown. And so because of the exciting opportunity to create a new class of medicine, we are very focused on managing the unknown technology risk.

And so we tried of those 6 technology in parallel, so we could learn from the clinic where to invest more because mRNA is an information molecule making it to platform, and wherever you wanted to fix. If you learn something about the science, fix that science if you can or decide that you are stop investing in that opportunity, you want to deploy your capital wisely where you know the technology is working. So that was kind of a premise as we started. And so what is happening with this pivot in the company history is that now we have a clinical data we gathered for prophylactic vaccine and systemic therapeutics. We believe those are core, i.e., in our opinion, we believe the technology risk is off the table, meaning we want to deploy our capital to make innovative medicine that goes to the clinic, because it's exactly the same technology, same manufacturing process than the ones we already have the positive clinical data.

On the exploratory front, yes, we want to be very cautious, and that has been the case for years. We say doing only one program per exploratory modality seems too risky for us because you have biology risk and there's always biology risk. But we always say a few -- 2, 3 programs kind of make sense for us, as what you see. So do we intend to invest more shareholder capital on more [infrastructure], more -- for example -- an example of 1 of the 4 exploratory right now? The answer is clearly no. We want to see what we get from OX40, IL-12 and the triplet. But like we've done with those 2 modalities that have migrated from exploratory to core in the last few months, if we get signal, the team has a lot of ideas of what other things we could do. And of course, then those programs where we get positive readout, we'll take those as fast as we can to BLA because those medicine will be needed for patients.

Stephen, you want to talk about RSV?

Stephen Hoge - *Moderna, Inc. - President*

Yes, just quickly on RSV. So Alan, as you referenced, we have a partnership with Merck in respiratory syncytial virus, just a monotherapy vaccine. There are 2 candidates in Phase I study. V172 is the one that is currently being conducted. And those are targeting the elderly target product profile. And so there is a nearly equal burden of disease in the elderly, 170,000 hospitalizations a year in this country. We're excited to be working with Merck in that elderly population. We have a right in our agreement, as we disclosed, to conduct development of an RSV vaccines towards a respiratory combination, and that had been our intent. And so we are -- that is separate from Merck's prerogatives in RSV.

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

Good. Thanks, Stephen. And on the last question, on manufacturing capacity. So maybe let me try to tease it out -- a pre-coronavirus world, which we talked about in previous calls and previous discussion, which is our manufacturing long-term plan is to use Norwood to make development material like we are doing today and to launch our commercial products like CMV, Zika and the others out of Norwood, because of how Norwood was designed. We've always said to manage financing risk, we do not want to invest in a big manufacturing capacity commercial plant until we are, of course, BLA approved, purely risk management. But we've always said our long-term vision is to have Norwood focus on development, so that we have a commercial site and hopefully down the road as we scale the company several around the planet that are just focused on commercial products. We believe, based on our experience in previous pharmaceutical companies, that having dedicated focus per site is really important for success.

Development requires nimbleness. Commercial requires scale and efficiencies. Very different worlds. So that's kind of a pre-coronavirus world, our previous plans. And the post coronavirus, while in the last few weeks, I go back to my previous answer a few minutes ago, which is we are looking at a lot of options, both internally, externally, CMO partners, to figure out what's the right path forward. And when we have a better picture, we will share it.

Operator

Thank you. That ends our Q&A session. I would now like to hand the call back to Stéphane Bancel.

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

Well, thank you for your question. Especially, thank you for your trust into our ability to make mRNA an important new class of medicines. We hope to see many of you next week in Norwood for what I believe will be an exciting Manufacturing and Digital Day. Thank you.

Operator

Thank you. This concludes today's conference call. Thank you all for attending. You may now disconnect.
