Q4 2019 Earnings Call

Company Participants

- Lavina Talukdar, Head of Investor Relations
- Lorence Kim, Chief Financial Officer
- Stephane Bancel, Chief Executive Officer
- Stephen Hoge, President
- Tal Zaks, Chief Medical Officer

Other Participants

- Alan Carr, Analyst
- Alec Stranahan, Analytst
- Cory Kasimov, Analyst
- Edward A. Tenthoff, Analyst
- Hartaj Singh, Analyst
- Matthew Harrison, Analyst
- Ross Weinreb, Analyst
- Yasmeen Rahimi, Analyst

Presentation

Operator

Good morning and welcome to Moderna's Fourth Quarter and Full Year 2019 Conference Call. At this time, all participants are in a listen-only mode. Following the formal remarks, we will open the call up for your questions. Please be advised that the call is being recorded.

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

Lavina Talukdar {BIO 19691239 <GO>}

Thank you, Operator. Good morning, everyone. On today's call, we will discuss Moderna's fourth quarter and full year 2019 business updates and financial results. You can access the press release issued this morning, as well as the slides that we'll be reviewing, by going to the Investors section of our website. Speaking on today's call are Stephane Bancel, our 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 Stephane.

Stephane Bancel {BIO 15174250 <GO>}

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 announce of working with the 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 two of the 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 two modalities that we now call core modalities. As a result, our strategy is to double down in these two commodities with many important medicines. We have already announced five new development candidates in this commodity since January 13th at the J.P.Morgan Conference. For new development candidates in the picture disease prophylactic vaccines and two in the systemic secreted and cell surface therapeutics modalities.

Why we double down in core modalities? We are still more than 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 these, we have two distinct businesses. This is significant point in our strategy. Core modalities. where (inaudible) can invest; exploratory modalities where we are waiting for clinical data to be cycled in the path forward.

So, stepping back. I would like to share with you the progression of the company to about 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 them on the science, formulation and manufacturing. The company devoted out of that growth phase when we enter the clinic, we will extend influenza vaccine in December 2015.

In the clinic, our next goal was to learn how well our technology was working on us. We explored our technologies across six different modalities. We tested 16 different (inaudible) in the clinic in the short four-year period. In 2019, we generated important data in two of these six modalities and I don't (inaudible) two core modalities. In picture, disease prophylactic vaccines and systemic secreted and cell surface therapeutics.

We are entering the new phase of the company's developments. Our goal for this next phase of our history is to file multiple BLAs while continuing to explore on the clinical programs in the four exploratory modalities. We are supportive to invest aggressively in our science, including investing in new modalities such as our ongoing collaboration with (inaudible). We are 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 the prophylactic vaccine programs.

Tal Zaks {BIO 19987702 <GO>}

Thank you, Stephane, and good morning, everyone. I'll start with a quick reminder on the data generated to-date with our vaccines. In over 1,000 healthy volunteers and six positive Phase 1 datasets to date, we have observed the 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 2 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 HD escalation study, and Merck is on track with their RSV program in adults.

Zika is also growing well, as three of the four dose cohorts have completed enrollment. Our three 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 has 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 neurodevelopmental disabilities. And in fact, the spectrum of the 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 seven-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 ten-

fold higher than the level seen in seropositives at baseline. We also saw a nice increase in titers against the fibroblast. Even in seropositives, people who have been infected, our vaccine is able to boost them 20- to 40-fold 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 2 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 3 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. That was an opportunity for us. CMV is clearly a blockbuster opportunity. We estimate annual peak sales for 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 have to make 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 one of the antigens in our vaccine, the gB, when encoded for in the 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 dose 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 {BIO 17925815 <GO>}

Thank you, Tal. I want to start by introducing the three development candidates in our vaccine -- prophylactic vaccines modality, that we've recently announced earlier this month. The first is against Epstein-Barr Virus. I 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 it spreads through bodily fluids, mostly in the young children and adolescents. EBV is a major cause of a wide range of diseases, but it is a 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. And then, 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 primary 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 would provide only partial B-cell protection, reduce the rate of infection in prior study by up to 7 -- reduce 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 of gp42, gH, gL and gB will provide an opportunity for broader protection, both of 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 reach almost $500 million annually, and the indirect cost 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 cirrhosis. These would represent a long-term potential, but are not currently a focus of our current clinical development plan.

Pivoting 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 five. Globally, the burden of the disease is even more substantial, with over 30 million episodes of acute lower respiratory tract infection annually. We estimate that the direct cost associated with pediatric RSV disease in the children under the age of five exceed $2 billion annually.

So, our target population for this vaccine is the young, under-the-age-of-five 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 tract and upper respiratory tract 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 and the Vaccine Research Center, which are both part of the NIH. The first clinical batch for our Phase 1, including finishing and filling of vials, was completed on February 7th. And earlier this week, that batch was shipped to the NIH for the Phase 1 study. NIAID will conduct that Phase 1 study under their own IND in the near term.

Now, pivoting to our second core modality. Earlier this year, we did announce two additional programs in the autoimmune therapeutic area, in our systemic secreted and cell surface therapeutics. And as we described them at J.P.Morgan, I won't go into great detail, but to briefly recap them here. 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 a non-human primate that 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 sent 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 or reestablishment of immune homeostasis in effector cells, including T-cells and B-cells. mRNA-6981 will be 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, the disease we see of compelling unmet need.

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

Tal Zaks {BIO 19987702 <GO>}

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 2 trial for the treatment of adjuvant melanoma and the combination of PCV with KEYTRUDA against KEYTRUDA arm and it's recruiting well.

KRAS vaccine, mRNA-5671, is in ongoing Phase 1 study. And this one is led by Merck and has monotherapy as well as the combination with KEYTRUDA alone. Our intra-tumor immuno-oncology therapeutics, we have three 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 matter will be helpful to these patients.

On the regenerative therapeutic modality, AstraZeneca is conducting a Phase 2a in the 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 two 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 are in the observation period right now. This trial is now open at seven 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, where we go from here.

Lorence Kim {BIO 18670491 <GO>}

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 three significant things from us today around the CMV vaccine, where the Phase 3 preparation is very much underway. You heard that Phase 2 enrollment for that CMV vaccine is ahead of schedule. And importantly, in Phase 1, 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 all heard that we announced in the first two months of the year five 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 is 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 2 data with a three-month interim analysis in the third quarter of this year and Phase 3 start in 2021. And with the rest of the vaccines, you'll see a number of additional Phase 1 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 in 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 will be filing a lot of new financial shortly with the 10-K.

We entered 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 a $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 were completed as of January 1st 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 four-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 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 is mainly due to a decrease in our in-licensing payments to Cellscript and its affiliate and a reduction of our lab supplies and materials. The increase for the full year 2019 is 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 three 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 with overall flat versus 2019 when we thought about expectations, even with the advancement of our pipeline through the clinic. And so the result will 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. With that, approximately $500 million of cash investment into our business is put in the context in the next slide, versus the cash that's available to us for investment.

Here, you see our year-end cash balance at $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 underwriters' 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 significant cash runway of multiple years.

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

Stephane Bancel {BIO 15174250 <GO>}

Thank you, Lorence, Tal and Stephen. On Slide 35, you can see a bit on Moderna's priorities. Our company has never been stronger. Our pipeline preparing for CMV Phase 3, (inaudible) preparing for Phase 2, the event Phase 1 trial is ongoing and 10 positive clinical readouts.

Our programs in development. Seven vaccines, where there are no approved vaccines on the market. Most of these vaccine candidates have multi-billion dollar annual peak sales opportunities.

As I shared in the 2019 shareholder letter, we believe our innovative vaccines are going to be very large business Moderna. With long-term annuity-like opportunity and a high EBIT margin, five immuno-oncology drugs in the clinic, five rare disease programs with first Phase 1 started finally, two autoimmune diseases program, the foundations of Moderna have been stronger. Our clinical experience is not more than one other 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 the 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 1 dosing in only 42 days. And we're proud to be included with those many companies working on the possible response to this continuing global health emergency.

Norwood is a fully digital, fully integrated facility that enable us to the execution of our pipeline, all the way from raw materials to finished products ready to ship to the clinic.

We have great partners with AZ, Merck and Vertex, (inaudible) 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 toward 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 number one, execute on our development pipeline with a special focus on CMV Phase restart. Priority number two is creating new development candidates in the two core modalities. We already have five in the last two months only. And priority number three is to develop new development candidates 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 2018 on the digital front, including use cases of artificial intelligence and machine learning.

We hope to host many of you for first Vaccines Day in New York City on April 14th for a deep dive into our mRNA vaccine modality. We will discuss some of our things, clinical data and 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 fourth R&D Day, where, as usual, in New York, we'll 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 (inaudible) multiple medicines, which we own commercially. And two, continue to explore modalities in the clinic and invest in science.

We have two core modalities and are now laser focused on filing multiple BLAs and then scaling will that to maximize the impact on patients. We're 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 medicines from the lab to approval will be materially higher than traditional medicines.

Speed. Our track record speaks louder than words. Coronavirus from sequence through shipping, clinical-grade product, 42 days. Evidence of greater capital efficiency relative to traditional recombinant technology is becoming apparent.

We can do new DCs 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 number two 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 of science or IP and the manufacturing site on Norwood, we will work to accelerate our leadership in the months and quarters to come.

We are excited about 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 sometime 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 will select to recognize all 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

Thank you. (Operator Instructions) Our first question is from Matthew Harrison from Morgan Stanley. Go ahead, your question please.

Q - Matthew Harrison {BIO 17603148 <GO>}

Hey, good morning. Thanks for taking the questions. I guess, two from 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 on CMV -- 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. Thanks.

A - Tal Zaks {BIO 19987702 <GO>}

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 I think we'll update everybody once we have a clear picture of that. Obviously, this is a rapidly changing environment.

On MMA enrollment. So right now, we've got one patient enrolled. We do not yet have the 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 three. 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.

Q - Matthew Harrison {BIO 17603148 <GO>}

Thank you.

Operator

Thank you. Our next question is from Ted Tenthoff of Piper Sandler. Your line is open.

Q - Edward A. Tenthoff {BIO 1880164 <GO>}

Great, thank you very much. And just following up on Matt's question first. What -- Maybe you can just remind us again so that everybody understands, because we've been 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? Thanks so much.

A - Tal Zaks {BIO 19987702 <GO>}

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 pathway to licensure are well understood and they encompass everything from finding circuits 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 circuit of protection because this is a very new virus and now 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 adolescence because, obviously, you want to start protection as early as possible given that's what -- the disease we're trying to prevent here is ultimately going to the infants born to women.

So, we're going to try and get down to that age group as we develop this vaccine.

Q - Edward A. Tenthoff {BIO 1880164 <GO>}

Okay, great. Thank you very much.

Operator

Thank you. Our next question is from Salveen Richter of Goldman Sachs. Go ahead please.

Q - Ross Weinreb {BIO 20445365 <GO>}

Thanks for taking the question. 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 the second dose? And are you guys seeing any signs that they can meet immune response? And then I have a follow-up.

A - Stephane Bancel {BIO 15174250 <GO>}

Good. So, it's Stephane. I will talk about, first of all, on corona. Our only focus as a team is public health. People are sick all over the planet, people are dying. The only focus is to get the vaccine as fast as we can, safely, partnering the right people to get it done.

A - Tal Zaks {BIO 19987702 <GO>}

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 onto -- in terms of where we are once I have a full sense of the data set there. I'll, of course, update everybody.

Q - Ross Weinreb {BIO 20445365 <GO>}

Great. And then just lastly. So, outside of the Phase 2 CMV the update in 3Q, what programs are you expecting to have data this year?

A - Lorence Kim {BIO 18670491 <GO>}

As you know, we don't guide to 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, it is a list that comprises all the next steps.

Some of those have advanced fairly far along. For instance, I would note that the Phase 1 vaccine studies for RSV and Zika have been running since last year, and other instances you will recall that, as you pointed out, the chikungunya antibody program is a relatively small study in healthy volunteers.

But again, we're focused on advancing all these programs as rapidly as we can towards data.

Q - Ross Weinreb {BIO 20445365 <GO>}

Great, thanks.

Operator

Next question is from Geoff Meacham of Bank of America. Go ahead, please.

Q - Alec Stranahan {BIO 20630524 <GO>}

Hey, guys. This is Alec on for Geoff. Thanks for taking our questions. Two questions from me. So, 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 1 for the PCV since ASCO? I'm 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 the next, a couple more.

A - Tal Zaks {BIO 19987702 <GO>}

Thanks, Alec. It's Tal. Look, on the personalized cancer vaccine. It's a Phase 1. So, data continues to come in. Once we have a full cogent dataset there, we will be disclosing it.

As the question to why we don't consider this a core, I think, for us, core is one that we have gotten the requisite from oncology 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.

Q - Alec Stranahan {BIO 20630524 <GO>}

Got it. That's very helpful. Thanks. 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 and others. So, any color you can give on this partnership would be great. Thanks.

A - Stephen Hoge {BIO 17925815 <GO>}

Yeah. We don't generally comment on research. 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

All right. Our next question is from Cory Kasimov from JPMorgan. Go ahead please.

Q - Cory Kasimov {BIO 3009346 <GO>}

Good morning, guys. Thank you for taking my questions. 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 2021 event. 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 2 will get in 3Q. Is this more or less to kind of looking to replicate the Phase 1 results in a larger group of patients, or are other nuances we should be thinking about? Thanks.

A - Stephane Bancel {BIO 15174250 <GO>}

So, Cory, good morning. It's Stephane. So, I'll take the first one on manufacturing capacity. I think the (inaudible) is just too early to know precisely because we don't know the dose. First, we don't have those, then fill finish, there's Norwood CMO capacity actually new sites. So, just way too early to comment on that. But, we're working out to get as much as we can.

A - Tal Zaks {BIO 19987702 <GO>}

Hi, Cory. It's Tal. Let me answer your question on CMV Phase 2. So, I think, in a nutshell, the goal here is, as you say, to replicate what we saw in the Phase 1. But I would like to be able to do that, of course, in the larger dataset so that our confidence in picking the right dose for Phase 3 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 Phase 3 trial.

Q - Cory Kasimov {BIO 3009346 <GO>}

Okay. Thank You.

Operator

Our next one is from Hartaj Singh of Oppenheimer & Company. Go ahead, please.

Q - Hartaj Singh {BIO 18796450 <GO>}

Great, thank you. I have just a question on CMV. With the Phase 2 results coming up in the third quarter and then the Phase 3 getting going, could you talk a little bit about how you could speed it to market? I know that a lot will be dependent on the Phase 2 results, but can you give us some sort of kind of a confidence in enroll as to when you think the Phase 3 could readout and by which time you could be in the market; 2024, '25, '26? And then just a follow-on to that, which is that you've (technical difficulty) opportunity of $5 billion, which seems to make a lot of sense 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? Thank you very much.

A - Tal Zaks {BIO 19987702 <GO>}

All right, Hartaj, this is Tal. Let me start by answering the first question. So, look, the timeline 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 two 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 two 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 timelines are pretty well understood for what's achievable in our industry. So, you can do the math from there.

A - Stephane Bancel {BIO 15174250 <GO>}

Yes. And -- Stephane, I'll take the second one on CMV; what we take to get to the $5 billion type of number. I think, a few things. The first one is, as we explained, the R&D Day in September, it will take -- get an indication approval in women in childbearing age, which, as you know, is our first one. Then, to get into an adolescent approval like the HPV, GARDASIL. And third is to get into pediatric. As we shared, humans are (inaudible) for CMV. We believe it is 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 this virus, which has a lot of long-term negative impact on health at a 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 in the market for next 10 years; or are we going to be with one competitor or two competitors or five competitors. I can come back on that if you are interested in going further. And then is population growth. There is a lot of emerging markets that's not only growing in size with our population growth, but also in terms of dollar invested in (inaudible) if you take about a five-year, 10-year, 15-year timeframe. And that's what impact the model that we've for getting to around $5 billion annual peak sales.

Q - Hartaj Singh {BIO 18796450 <GO>}

Great, thank you.

Operator

Our next question is from Yasmeen Rahimi of ROTH Capital Partner. Go ahead, please.

Q - Yasmeen Rahimi {BIO 20388907 <GO>}

Hi, team. Thank you for taking my questions and thank you for the tremendous progress that you're making quarter-over-quarter. 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 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 3?

And then a second question that was often that is, as you're in a predominant part of being able to scale up and we're going to learn more in manufacturing on March 4th, can you enlighten us what are aspects that are unique when you're scaling up in mRNA therapeutic versus other RNA modalities? Just so we have a little bit of color (inaudible) looking for you. And thank you for taking the questions.

A - Tal Zaks {BIO 19987702 <GO>}

Hi, Yasmeen, it's Tal. Let me take your first question. It's a great question and 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 our literature that there is a high level of variability. And it's not just on a Continental level, U.S. versus Europe, but it is actually local geography, 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 site and population 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 will -- ultimately, the trial size will come down to the number of cases. And that's one that you can monitor in almost real time.

A - Stephane Bancel {BIO 15174250 <GO>}

So, good morning, Yasmeen, it's Stephane. 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-phase process to make mRNA, which is (inaudible). So, that drives to a very small reactors compared to other technologies, especially compared to recombinant is the most staggering changes than through for given output just the size of a reactor, which, of course, has a big impact on your CapEx, including all your purification technologies because you just have less lead to go for the (inaudible) zone. So, everything is much, much cheaper across the board. As we talked in the past, because mRNA is a new formation molecule. It is the same process for (inaudible) CMV or for coronavirus. So drives incredible flexibility and incredible time to the clinic because we do not have to invent the process for every vaccine or every molecule as the team has shown in the last two weeks with coronavirus. If we've had like traditional technologies to invest 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 that case, we are able to just do a tiny bit of optimization for a very large molecule that this mRNA is. And then go right into production. Thanks to this aspect of a platform that we have. And (inaudible) time to make mRNA is days, not weeks.

And so when you think about that, we can use an asset. I mean, once you make (inaudible) you can basically change with this possible equipment and use the same room or the same team to make another product. And so if you can deliver in a few days, make

mRNA versus a few weeks to make component before you're going to go into fill finish. That's a massive use of your capital infrastructure in terms of just CapEx turnover.

Q - Yasmeen Rahimi {BIO 20388907 <GO>}

Thank you, team, and look forward to seeing you in Boston.

A - Stephane Bancel {BIO 15174250 <GO>}

All right.

Operator

Thank you. (Operator Instructions) And next one is from Alan Carr of Needham. Please go ahead.

Q - Alan Carr {BIO 15355437 <GO>}

Hi, thanks for taking my questions. 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 your overall manufacturing capacity at the Norwood facility right now across all programs, the total capacity? And without regard to coronavirus, what are your long-term plans in terms of your needs for capacity in terms of adding manufacturing capacity in the long term?

Thanks.

As you go commercial.

A - Stephane Bancel {BIO 15174250 <GO>}

Good. Thanks for those three questions. So, let me take the first one, on exploratory and core. So, yes, if you go back to the strategy, we started with six 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 those six technology in parallel. So, we could learn from a clinic where to invest more, because mRNA is a new formation 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're 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 that now we've clinical data we gathered for prophylactic vaccine and systemic therapeutics. We believe those are core; that is, 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've variety risk and there is always variety risk. But we always say that two free products kind of makes sense for us, as what you see. So, do we intend to invest more shareholder capital on more intratumoral, for an example, one of our four 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 two modalities thats 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 program where we get positive signal, we'll take those as fast as we can to BLA, because dose of medicine would be easier for patient.

Stephen, do you want to talk about RSV?

A - Stephen Hoge {BIO 17925815 <GO>}

Yeah. 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 two candidates in Phase 1 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 agreements, as we disclosed, to conduct development of an RSV vaccines towards a respiratory combination and that has been our intent. And so we are -- That is separate from Merck's prerogatives in RSV.

A - Stephane Bancel {BIO 15174250 <GO>}

Good. Thanks, Stephen. And on the last question on manufacturing capacity. So, let me try to (inaudible). In a pre-coronavirus world, which we talked about in previous calls or in 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 Norwood design. We've always said to manage financing rates, we do not want to invest in a big manufacturing capacity commercial plant until we have, of course, BLA approved. Clearly, 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 very 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 (inaudible) a few minutes ago, which is we are looking at the law 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.

Q - Alan Carr {BIO 15355437 <GO>}

Great, thanks for taking my questions.

Operator

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

A - Stephane Bancel {BIO 15174250 <GO>}

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.