Q2 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

- Andrea, Analyst
- Cory Kasimov, Analyst
- Edward Tenthoff, Analyst
- Hartaj Singh, Analyst
- Jennifer, Analyst
- Matthew Harrison, Analyst
- Unidentified Participant

Presentation

Operator

Good morning, and welcome to Moderna's Second Quarter 2019 Conference Call. (Operator Instructions)

At this time, I'd 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, and welcome to Moderna's Second Quarter 2019 Conference Call to discuss business updates and financial results. You can access the press release issued this morning as well as the slides that we will be reviewing by going to the Investors section of our website at www.modernatx.com.

Today, on this call, we have Stephane Bancel, our Chief Executive Officer; Stephen Hoge, our President; Tal Zaks, our Chief Medical Officer; 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. We believe mRNA as a potential to be a new class of medicines. We believe our mRNA medicines have the potential to address large unmet medical needs and to treat diseases that are not addressable by recombinant proteins or small molecules. Due to the platform nature of mRNA, we believe our mRNA medicines provide a higher probability of technical success and faster time-lines to clinical trials and to the market relative to traditional medicines.

We also believe that the manufacturing capital intensity of mRNA is materially lower than recombinant proteins. and as the manufacturing cost at commercial scales will be similar to small molecule injectable. Because of this loss potential, we continue to focus on managing risk, across our portfolio, especially technology risk and biology risk. We believe that programs within the same modality have similar technology risk, meaning that once we de-risk a sentinel program, they are important breakthroughs. As a key example in the near future, we believe our chikungunya antibody program will be an important clinical readout, as it uses the same formulation technology as our MMA program, our most advanced rare disease candidate.

Our corporate focus is on three priorities: first, to execute on the development pipeline; two, to move new development candidate in existing modalities from the lab into the clinic; and three, to invest new development candidates in new modalities. I will review now our most important progress, since our last quarterly update in early May. Starting with PCV, personalized cancer vaccine, we've presented positive interim Phase 1 data at the ASCO meeting in June. And since, we are happy to report today that since ASCO we started a Phase 2 head-to-head trial in the adjuvant melanoma setting. We look forward to the readout of this important immuno-oncology program to assess if PCV plus Merck's KEYTRUDA can increase recurrence-free survival versus KEYTRUDA monotherapy. We're happy to report through there, that of Phase 1 for CMV as completed enrolling healthy subject at doses up to 300 microgram. We believe CMV is a large unmet medical need and we look forward to reviewing and sharing the Phase 1 trial data in the near term.

The team continues to execute at a rapid pace in the last 90 days. We advanced four new programs into Phase 1 since our May call. Two programs in immuno-oncology, started those in cancer patients. Our KRAS vaccine, which is partnered Merck and the IL12 intratumoral program which is partnered with AstraZeneca. Those are first patient. Two programs in infectious vaccine started dosing as well, our RSV vaccine mRNA-1172 partnered with Merck and our Zika vaccine mRNA-1893, which is funded by the US Agency BARDA.

Finally, I'm happy to report that clinical site are now open and actively recruiting patient in our first rare disease programs MMA. We have three open sites in the US and in the UK.

The clinical trial application all sit here, but just opened by local authorities. I am very pleased with the company's progress and I'm very thankful for our team dedication to this execution. We have five immuno-oncology programs in the clinic, including PCV in Phase 2 and OX40 soon entering Phase 2.

We have five important rare disease program and our team is working out to build the first MMA patients and to submit INDs for other rare disease programs. We have four vaccines in the clinic for major unmet medical needs, CMV, RSV, hMPV PIV combo and Zika. I want to remind you that there are no approved vaccines for any of these harmful pathogen that severely affect thousands each year. We are very pleased to have completed enrollment in our CMV trial and we look forward to sharing the data we used on. The company has never been as strong and we're all focused on continuing to execute and share our progress in the months to come.

With this, let me turn to Tal to give you some more color on the development pipeline.

Tal Zaks {BIO 19987702 <GO>}

Thank you, Stephane. As you know, we're advancing our pipeline of medicines in six different modalities. And then, in the next few slides we will highlight the progress we've made this quarter in each of these. So starting with the Prophylactic vaccines on Slide 13, you will see, we have eight programs in this modality, and we've made significant progress in the last quarter. In total, today, we have safety data from over 100 healthy volunteers who have participated in our Phase 1 studies and we remain pleased with the emerging safety and tolerability profile of our vaccines.

I'm happy to report that our CMV program with mRNA-1647 is now fully enrolled in the Phase 1 trial, and I'll go over this opportunity in greater detail in just a moment. The RSV Phase 1 study testing mRNA-1172 dosed its first subjects in this quarter and recall that at the last quarterly update we reported that our partner Merck has just filed the IND.

Our Zika program with mRNA-1893 also have the IND filed an open in the second quarter and I'm happy to report that the first subjects in the Zika Phase 1 trial was also dosed. In terms of emerging data and hMPV and PIV3 or mRNA-1653, we continue to see neutralization titers above baseline at the second interim look seven months after the last vaccination. For context, in January, reported the two month immunogenicity data. We plan to present the full data from this Phase 1 study at ID following -- ID week in the fall.

We're also pleased with the feedback from FDA regarding the development plans for mRNA-1653, where we discuss the potential paths forward to evaluate protection against both hMPV and PIV3 in a single Phase 3 study. Consistent with these plans we plan to enroll seropositive toddlers in our next trial.

Finally, the Phase 1 data for Influenza vaccines against H7 and H10 were published in the Journal vaccine. Let me now spend a few minutes on CMV. As noted before the Phase 1 trial for CMV is fully enrolled, CMV is a common pathogen that is a leading cause of birth defects. The burden of disease is significant were approximately 25,000 newborns are

infected each year in the US alone. Currently, there aren't any vaccines against the CMV virus on the market. That's because CMV is proven to be a challenging vaccine, a manufacturer using traditional technologies. Given the structure of one of the antigens the pentamer which we think is required to a listed protective immune response. We believe these challenges can be overcome with our mRNA based vaccine as our technology lends itself to producing the pentameric viral antigen by encoding for the simultaneous translation of its five components.

As a reminder and is shown on Slide 15, mRNA-1647 actually contain six mRNA sequences, five of which encodes for this pentamer and one that encodes for the GB protein. We believe the combination of these two antigens encoded by mRNA-1647 will produce potent and durable antibody titers against CMV that have the potential to protect against infection. We look forward to the Phase 1 results soon.

Let me now turn to cancer vaccines. You will see the programs in this modality on Slide 17, and I'll focus on mRNA-4157 are personalized cancer vaccine and on the KRAS vaccine mRNA-5671. We recall that we and our partner Merck announced the Phase 2 trial earlier this year. The Phase 2 design is a randomized trial testing the combination of mRNA-4157 in combination with pembrolizumab against a pembrolizumab monotherapy control arm in high risk melanoma patients in the adjuvant setting.

I'm happy to report today that the Phase 2 is up and running and that the first patients have consented to the trial. Interim safety tolerability and immunogenicity data from our Phase 1 where the basis for the decision to move to Phase 2. We presented these interim data with mRNA-4157 either as a monotherapy in a respected adjuvant population or in combination with pembrolizumab in the metastatic setting. These two arms represent arms A and arms B, respectively of the Phase 1 study. We have a Part C and Part D that continue to enroll. Our T [ph] histologies includes micro satellite stable or MSS colorectal cancer and head and neck squamous cell carcinoma. We and our partner Merck have also added an additional cohort in Part B where we will be testing the combination of mRNA-4157 with pembrolizumab in patients who are refractory to PD-1 inhibitors.

Turning now to the interim results we presented at ASCO of this year, we showed that mRNA-4157 was safe and well tolerated with no reported DLTs and no Grade 3 or Grade 4 adverse events. We also show that mRNA-4157 elicited new antigens specific T cell activation in 10 of the 18 Class 1 neoantigens and the one patient treated at the top dose where apheresis was performed. While these data were obtained with the first version of our vaccine that included up to 20 neoantigens, we're not selecting for up to 34 neoantigens using our proprietary algorithm.

For the data presented at ASCO, the patients were dosed with the PCV that had the 20 neoantigens and all patients who have enrolled since April in both the Phase 1 and Phase 2 studies have been receiving the 34 neoantigens version. At ASCO, while the clinical data are early and preliminary, we did report six responses in Part B of the study in the metastatic setting. One of these with the complete responded to pembrolizumab monotherapy prior to receiving the personalized cancer vaccine, and five other dose with the combination of mRNA-4157 pembrolizumab had a partial response. Two of these five PRs were patients who were previously treated with checkpoint inhibitors. While these

early signals are trending in the right direction, we believe that our Phase 2 trial will help us and Merck to definitively ascertain the incremental benefit of mRNA-4157.

Moving now to the KRAS vaccine, I'm also pleased to announce that the first patient in our Phase 1 trial testing KRAS vaccine mRNA-5671 dosed. As a reminder, KRAS is a key regulator of cell proliferation and survival; mutation and the KRAS gene cause dysregulated cell proliferation and it's one of the best studied oncogenes. It is the most commonly mutated oncogene and it drives over 20% of human cancer is predominantly in the pancreatic lung and colorectal cancers. Indeed the team at the NCI led by Steve Rosenberg had shown at the end of 2016 that the recognition of the mutated KRAS epitopes by T-cells can lead to cancer regression.

A quick overview of mRNA-5671 is shown on Slide 21. It includes for the four most prevalent mutations of KRAS, which together represent 80% to 90% of KRAS mutations. The genetic sequences that spend the mutations are combined into a single mRNA that encodes for all four neoantigens. When translated within the cell into neoantigen protein chain, the cellular (inaudible) machinery is expected to clear the chain and present these new antigens to the immune system to stimulate what we hope will be an active anti-cancer T-cell response.

The Phase 1 trial for this vaccine which is being run by our partner Merck has enrolled its first patient. And this study will evaluate safety and tolerability of mRNA-5671, both as monotherapy and in combination with KEYTRUDA in patients with metastatic non-small cell lung, colorectal and pancreatic cancers that harbor the KRAS mutations. Of note in this trial, we are selecting for specific HLA subtypes that based on the signs are most likely to respond.

For the Intratumoral Immuno-Oncology programs, we're progressing with all three of our development candidates, OX40 ligand, the Triplet and interleukin 12. Starting with mRNA-2416, which encodes for OX40 ligand, which you will recall is a potent co-stimulator that promotes T-cell proliferation. The Phase 1 is completing the dose confirmation court at 8 milligram and in parallel we are progressing to start the Phase 2 cohort in patients with advanced ovarian cancer.

Slide 26 shows a schematic of the Phase 1 trial and the Phase 2 cohorts. Turning to mRNA-2752 or the Triplet which encodes for OX40 ligand and to pro-inflammaotory cytokines interleukin 23 and interleukin 36 gamma. The rationale here is to stimulate T-cells through the presence of OX40 ligand while attracting the T-cells to the tumor site with the local expression of the cytokines. By injecting the tumors directly we expect the cytokines acts locally within the tumor microenvironment.

The Phase 1 is ongoing and has both a monotherapy are and a combination arm with development. I'm pleased to report that the first patient in the combination arm with development has been dosed. We've also made progress with MEDI1191 in our interleukin 12 into tumor injection program partnered with AstraZeneca as the first patient in this trial was dosed. Recall and interleukin 12 is a potent immune modulator associated with a type 1 interferon response and production of interferon gamma. Its activity against cancer has

been described in the literature, but safety has been a problem when interleukin 12 has been administered systemically. We believe that the intratumoral mRNA approach should allow for interleukin 12 to act local in the tumor microenvironment, while avoiding the toxicity seen with the systemic administration.

Let me touch for a moment on the localized regenerative therapeutics and AZD801. The Phase 2A in coronary arterial bypass graph population is ongoing. Our partner AstraZeneca continues to open additional sites in Europe with a clinical trial application also open in Germany. Let me move ahead to our systemic secreted therapeutics and I will focus on mRNA-1944. Our antibody against the chikungunya virus. As of today, we have enrolled six of the eight subjects in the third dosed cohort. Before I get to the trial design in the strategy around this program wanted to take a few minutes to highlight the program, which is DARPA funded. mRNA-1944 encodes for an antibody against chikungunya. Now, antibodies are complex protein that require both heavy and light chain to come together to form an active protein. So mRNA-1944 actually includes 2 mRNAs and one that encodes for the heavy chain and one that encodes for the light chain. Once formed we're expecting antibody to be secreted into the bloodstream, where we will be watching to see if it confer passive immunity against the chikungunya virus as expected.

On the Slide 36, you will see the trial design. The key objectives of the trial are to evaluate the safety and tolerability of four single-ascending doses of mRNA-1944 and to evaluate the pharmacokinetics of the drug and the pharmacodynamics of the anti-chikungunya virus antibody levels, which together will describe the dose response curve. We are collecting assay data to see if the antibody levels neutralize the virus, which we believe will ultimately speak as to whether or not this antibody we encode for is indeed functional.

The utility of this program is really 2-fold one, first as a product that could potentially protect against chikungunya infection by conferring passive immunity. And second, as this program uses the same lipid nanoparticle formulation that is shared with our other programs in the rare disease indications that we're pursuing it could inform the risk profile of those other programs as well.

Lastly, on systemic intracellular therapeutics, where we have four development candidates. I'll highlight our rare disease programs methylmalonic acidemia or MMA and the closely associated disease propionic acidemia or PA. Both MMA and PA or inborn errors of protein metabolism that are caused by mute enzyme deficiency and PCC deficiency respectively. As you can see these two acidemia is a really on the same metabolic pathway. The prevalence of both is approximately 325 to 2,000 patients in the US, patients are identified during newborn screening and current regimens are palliative they consist of strict diet restrictions and oral and IV medications. Really the best treatment that we currently have available for suitable patients today is a liver transplant.

Both mRNA-3704 an mRNA-3927 in code for intracellular proteins that act within the liver cell and act on the mitochondria. Both programs also have FDA orphan drug designation, EMA orphan drug status and FDA rare pediatric disease designation, which upon approval will qualify the two programs for rare pediatric disease vouchers. The Phase 1

study of our sentinel rare disease program and MMA with mRNA-3704 currently has three sites open and we are actively recruiting patients. In parallel the natural history study continues to enroll well with a total of 71 patients across for MMA and PA enrolled.

Let me close with Slide 42, which shows you the breadth of our pipeline in one place. You will see all the new updates we've announced since December 2018 when we became a public company. And with that, let me turn the call over to Lorence.

Lorence Kim {BIO 18670491 <GO>}

Thanks, Tal. In today's press release, we reported our second quarter 2019 financial results. Please note these results are unaudited. We had in Q2 2019, the cash, cash equivalents and investments of $1.44 billion, this compared to $1.69 billion at the end of 2018. We are reiterating today our expectation for cash, cash equivalents and investments at December 31, 2019 to be in the range of $1.15 billion to $1.20 billion consistent with the guidance given on our call in March. We remain focused on allocation of our shareholder capital towards value driving investments in our portfolio and platform.

Net cash used in operating activities was $256 million for the first six months of 2019 compared to $160 million in 2018. These numbers include $22 million and $25 million of in-licensing payments in the first quarters of 2019 and 2018 respectively, as said it in the footnote. After the first quarter of 2019, we have no further in-licensing payment obligations to Cellscript and its affiliate.

Cash used for purchases of property and equipment was $18 million in the first six months of 2019 compared to $66 million in 2018. And then on revenue recall that on January 1, 2019, we adopted the mandated revenue recognition standard ASC 606, using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. The decrease in total revenue for Q2 in the first six months of 2019 as compared to 2018 was mainly attributable to this adoption of the new revenue standard.

Revenue for Q2 2019 was $13 million as compared to $29 million for Q2 2018. And for the first six months of 2019 revenue was $29 million compared to $58 million in 2018. Total revenue under the previous revenue recognition standard would have been $17 million for Q2 2019 and $55 million for the first six months of 2019.

R&D expenses for Q2 2019 were approximately $128 million compared to $104 million for Q2 2018. And for the first six months of 2019, R&D expenses were $259 million compared to $195 million in 2018. The increases in Q2 in the first six months of 2019 as compared to 2018 were primarily due to an increase in personnel related costs including stock-based compensation, an increase in clinical trial and manufacturing costs, an increase in lab supplies and materials, and an increase in consulting and outside services.

G&A expenses for Q2 2019 were approximately $29 million compared to $21 million in Q2 2018. And for the first six months of 2019, G&A expenses were $56 million compared to $38 million in 2018. The increases in Q2 in the first six months of 2019 as compared to

2018 were mainly due to the additional cost of operating as a publicly traded company, including an increase in personnel related costs and stock-based compensation consulting and outside services and insurance costs.

And with that, I'll hand the call back over to Stephane.

Stephane Bancel {BIO 15174250 <GO>}

Thank you, Lorence. To close our remarks, I would like to reiterate that our team is focused on executing our food priorities. I don't think the development pipeline inventing new development candidates in the existing six modalities and inventing new modalities. The team as Moderna, executives across the board during the quarter. To summarize quickly the highlight of the quarter. We initiated the PC Phase 2 trial with first patient costs I think to participate in the trial. Or CMV vaccine study is fully enrolled. We saw this 4 new clinical trials, two in immuno-oncology and two in infectious diseases. That Vertex cystic fibrosis and research collaboration.

As you might recall in July 2016, Moderna and Vertex announced an exclusive research collaboration and licensing agreement aimed at the discovery and development of mRNA therapeutics for the treatment of CF. Based on preclinical work to date, Vertex has extended this collaboration through the first quarter of 2020 with options to extend further based on future progress. Pulmonary mRNA delivery represents a potential new route of administration for Moderna.

I am pleased with the progress we've made to date and look forward to the rest of 2019 and 2020 as we are approach critical data readout. I would particularly look for CMV Phase 1 data and the chikungunya antibody Phase 1 data in the near term. As a reminder, the chikungunya antibody is the first monoclonal antibody encoded by mRNA technology to be dosed in a human. Because RSV and Zika are those in healthy subjects this trial should complete soon and if positive, we intended to central Phase 2.

We now have five immuno-oncology programs in the clinic. Two of which are already dosing in combination with the approved checkpoint inhibitors and (inaudible) PCV and AstraZeneca IMFINZI for triplet. Our teams working with clinical trial sites are focused on the milestone of dosing our first patients with MMA. We believe mRNA as a potential to be a new class of medicines. We see a large product opportunity ahead of us and we are energized about the potential to bring these important medicines to patients. Four vaccines fall off unmet medical needs where there is no vaccines approved to there. That is a unique opportunity towards millions and as such create large commercial products. Five immuno-oncology programs which all have the potential to improve the response of PD-1 of Period-1 checkpoint inhibitors.

(inaudible) disease programs for clinicians like MMA and PA, where childrens born with a missing or defective protein, urgently need a treatment that addresses the underlying cause of the disease. The cardiology program VEGF which could transform the (inaudible) patients we have sub filled in MMA. And this is only the first wave of innovative products.

Stephen Hoge and his team are working hard to move a new innovative development candidates from Vertex into the clinic.

The productivity overall I might have that probably significance with those of first clinical trial in December 2015. In just 3.5 year we started 16 programs in the clinic, and we've had a high success rate. The team did get 19 IND or CTAs operated by local authorities. We know we have a special opportunity and we are committed to delivering on the promise of our science and bringing forward a new class of medicines for patients.

I would like to hand over to Mark by thanking the many people who participate in our clinical studies including patients, healthy volunteers and physicians. I will also like to thank the great team of Moderna employees working hard every where to make our vision a reality. With that, we are now happy to take any question.

Questions And Answers

Operator

(Operator Instructions) Our first question comes from Salveen Richter of Goldman Sachs. Your line is open.

Q - Andrea {BIO 3266327 <GO>}

Great. Thanks for taking our questions. This is Andrea [ph] on for Salveen. My first one is, how are you thinking about positioning for your KRAS vaccine in the context of growing competition in the season. And then I have a follow-up.

A - Tal Zaks {BIO 19987702 <GO>}

Hi, this is, Tal. Thanks for the question. And look, first of all, I am really happy that we finally have therapies that are emerging as effective against KRAS mutations. I think that progress for the field is tremendous. I think, it's still early days. So let me make two points. First, the exact nature of the activity and against which mutations and in our case which mutations in which HLA's still needs to be defined. So I don't see them even on -- if you look at the patient distribution necessarily as competing.

Second, and I think, more importantly on the fundamentals, I think what our vaccine is trying to do and what the emerging inhibitors are trying to do are very different things in terms of patient benefit. I think the history of small molecule targeted therapies has been terrific in the sense that it's translated into real benefit for these patients. But we struggled to turn them into (technical difficulty) and treatments. I think on the other hand, the immuno-oncology approaches were successful have translated into a much more durable effect. And so my expectation is down the road if both of these approaches are successful, you would expect them to have complementary benefits for the patients and -- yeah, I'm really excited in the coming years to see how that story plays out.

A - Stephane Bancel {BIO 15174250 <GO>}

And maybe, it's Stephane, (inaudible) I think as Tal described in his remarks, the amount [ph] that we designed is actually calling for mutation, G12D, G12V, G13D, and G12C.

Q - Andrea {BIO 3266327 <GO>}

Great. And then just on your MMA program, how many patients right now are enrolling in your clinical study that have been rolled or from the natural history study?

A - Tal Zaks {BIO 19987702 <GO>}

So in the clinical study, we have not yet enrolled are active in recruiting in the natural history study, there have been 71 patients enrolled to date.

Q - Andrea {BIO 3266327 <GO>}

Sorry. Do you anticipate, I guess, rolling any patients over from that natural history study here or now.

A - Tal Zaks {BIO 19987702 <GO>}

It is a possibility. We're looking at it.

Q - Andrea {BIO 3266327 <GO>}

Got it. Thank you so much.

Operator

Our next question comes from Matthew Harrison of Morgan Stanley. Your line is open.

Q - Matthew Harrison {BIO 17603148 <GO>}

Hey, good morning. Thanks for taking my question. Two from me. So the first one is, can you just comment broadly how we should think about safety so far in the chikungunya study, given that you're through almost a third cohort. I don't know if you can comment on what the staffing is our from us from a safety standpoint. And then second question on OX40 ligand. Can you talk about what you need to do in the Phase 2 study, to be able to keep that the FDA, I mean, I guess I'm asking how should we think about potential regulatory path forward with that molecule. Thanks.

A - Tal Zaks {BIO 19987702 <GO>}

Sure. Look on -- let me start with the chikungunya. This study is ongoing. So I can't really comment on the data until we see the totality of the picture there and then we'll describe it for you. It's a healthy volunteer studies of stopping rules are what you would expect in these typical studies. In terms of OX40 ligand, the regulatory path. If you look at where we're expanding into the Phase 2 cohort, we're going after ovarian cancer. I think in that setting checkpoint inhibitors are not yet approved. And so, if we can -- and it's because they really have marginal activity as a monotherapy. If we can demonstrate that the combination has a clear benefit to patients, I think the path to approval will be relatively

straightforward. So that's how we're looking at it. Did that answer your question, Matthew?

Q - Matthew Harrison {BIO 17603148 <GO>}

It did. Thanks, Tal.

Operator

Our next question comes from Ted Tenthoff of Piper Jaffray. Your line is open.

Q - Edward Tenthoff {BIO 1880164 <GO>}

Great. Thank you very much and thank you for the update. Lots of good progress. So my question is and I apologize if this was asked, but with respect to the triple, my concern here is certainly not activity especially with (inaudible) but are you doing any special immune safety analysis or any special additional safety analysis just because of the potential potency of the triple therapy. Thanks.

A - Tal Zaks {BIO 19987702 <GO>}

Yeah, thanks. That's a really good question and which I had a wiser answer for you. The reality is that we're looking at the safety, I think in the traditional way that people do in clinical trials may be colored by a better understanding over the years of what the safety profile of the checkpoint inhibitors alone is. And so we're looking for whatever autoimmune phenomenon etc and all the other adverse events that one would expect from checkpoint inhibitor monotherapy and assessing very carefully to see whether we exceeded. If there is any other safety signal that is attributable to the triplet, then I think we've got two ways of finding it. First, recall we're dosing as monotherapy. So that will give us a clear view on the safety profile, just of the triplet. And second, in the combination arm, we're looking carefully at all the clinical characteristics. And unfortunately, I think is a field, it's very hard to predict the adverse reactions that one sees and they're not very frequent. So all you can do at this point is to maintain a careful visual for what's expected and make sure you're not missing anything unexpected. I don't know if that answers the question on, I'm not sure I get a better one.

Q - Edward Tenthoff {BIO 1880164 <GO>}

That's all right. That makes a lot of sense. I appreciate that. And then just a really quick high-level question. With respect to the CF collaboration, are there any novel delivery modalities that are being incorporated for that disease or is this really that not just treating well, but really systemic disease. Thank you.

A - Stephen Hoge {BIO 17925815 <GO>}

So. Ed, it's Stephen Hoge. I am -- so first of all, we're -- it's a research collaboration with Vertex, and we're excited to continue it based on the preclinical progress to date. As a part of our general research activities, we do look broadly at a range of different delivery modalities. We have obviously made progress in one direction here, but we haven't yet defined a development candidate, at which point we probably provide specifics about

that. Generally our approach with Vertex and CF has been to address the unmet need in CF, particularly for those patients who are also -- for CFTR and focusing intensively on the pulmonary disease. But obviously, without commenting specifically in the CF, example, pulmonary delivery is the route of administration that could be valid for other systemic diseases or other applications as well.

Q - Edward Tenthoff {BIO 1880164 <GO>}

Thanks, Lorence. Looking forward to the --

A - Tal Zaks {BIO 19987702 <GO>}

Yes, sorry go ahead.

Q - Edward Tenthoff {BIO 1880164 <GO>}

Great. I've some great imported CMV data, and see you guys in September. Thanks.

A - Stephane Bancel {BIO 15174250 <GO>}

Thank you.

Operator

Our next question comes from Cory Kasimov of JPMorgan. Your line is open.

Q - Cory Kasimov {BIO 3009346 <GO>}

Hey, good morning, guys. Thanks for taking my questions. I have two as well. So I guess, first, if he is walk us through the cadence of what you see as the key validating clinical updates we should expect in the next 12 months or so. Beyond that the CMV and chikungunya updates, what else has a chance of occurring in that time period. And when we see new clinical data at your R&D Day in September. And then I have one follow-up.

A - Stephane Bancel {BIO 15174250 <GO>}

Cory, good morning. It's Stephane. So I will not comment on beyond you there. I hope you come to the R&D Day. We will make sure that we give a good update on everything we know them. On the next 12 months, as you can see on Slide 46 on the presentation. As I discussed in my comments, CMV is very important as you know, we believe is a very large opportunity. We own 100% of the economic of these products. We believe there is very large medical needs out there. And so the CMV data are going to be very important we believe to the company.

INC and Zika, because that in Phase 1 healthy subject and the other thing as we speak should read pretty quickly, and thus I share the plan is to remove those to Phase 2, assuming we have good data into the clinic. I remind you that to -- we have already in the past shown in a good transition from primate into humans into our vaccines about positive data, and so we look forward with these data in human.

PCV, of course, we take a little a bit of time, because we started the Phase 2 that the important study with recruit for the Phase 2 on 50 patients across the globe and then it's basically of course looking at (inaudible). KRAS is going to be interesting. We all believe there is a big medical need and it will be tumor types. So we have directly into patients in Phase 1, so will be sharing observation at the advanced clinical meetings what we see in the clinic.

In the interest overall, because it's oncology and (inaudible) we prepared it in combination with a PD1 OX40 would be in Phase 2 soon. And also will be in combination with checkpoint and (inaudible) same thing we will update the advanced medical meetings and clinical observation except is recruiting. And then as we discussed the chick [ph] antibody is very important for us and then getting the (inaudible) in the clinic. The right things are going to go strictly to patients as we commented before we are starting MMA at a dose that has been showing newer models having some benefit. And so I think the next few months and the next few quarters are going to be quite rich data wise. We have now (technical difficulty) in the clinic. That's a lot of potential data readout.

Q - Cory Kasimov {BIO 3009346 <GO>}

Okay. Great. And then the follow-up is regarding your personalized cancer vaccine 4157 program. Any near-term plans for exploring indications beyond resected melanoma patients that are at high risk of relapse or PD1 refractory. What do you see is the potential of this program and indications that had that may have considerably -- of considerably less new appetites.

A - Tal Zaks {BIO 19987702 <GO>}

Thanks for that. Cory, it's Tal. It's a question that we've asked ourselves since the beginning of this program. I think, strategically and philosophically what we want to do with this program is first to go where the likelihood of success is the highest before we look for areas that are more challenging. And so that's why we focused in the histologies that we have in the Phase 1 and that's why we went to an adjuvant setting even within melanoma for a definitive study the Phase 2. I think once we have clear proof-of-concept. Clearly, we will begin to explore some of those additional indications. But there is not any current plans to do that.

A - Stephane Bancel {BIO 15174250 <GO>}

And maybe Cory, it's Stephane, who has to tell us remarks. If you think about it going back to Lorence comments, we are very keeping capital allocation. So, of course, it could be a lot of different things one could think of trying with personalized cancer vaccine as you think about all the patient at the untreated there, but unfortunately we cannot -- before we have an important risking we cannot expand too much, because we have so many opportunities of products across the portfolio, we could be increasing the balance to a play that will not be reasonable. And so we want to be very disciplined. As a just one example, there is a lot of things, trust me, that the clinical team, as you know, (inaudible) we love to be trying effect to help those patients. But we just have to be very disciplined capital allocation and how much we spend and where we spend it and when we spend it based on the risking.

Q - Cory Kasimov {BIO 3009346 <GO>}

Okay. Makes a lot sense. Thanks for taking the questions.

A - Stephane Bancel {BIO 15174250 <GO>}

Thank you.

Operator

Our next question comes from Alan Carr of Needham. Your line is open.

Q - Jennifer {BIO 1827328 <GO>}

Hi. This is Jennifer speaking for Alan. I have a couple of questions. The first question is, I was wondering if the team can you give us some color on the commercial strategy and possibly the specific patient groups that you may be planning to target for the CMV assets. Thank you.

A - Stephane Bancel {BIO 15174250 <GO>}

So thank you, Jennifer for question. I think it would be great if you can join us have the R&D Day, because we will spend quite some time on CMV commercial opportunity. As we discussed in the past, there are many populations from women in the age of bearing a child, adolescents women that you might want to protect, there is a discussion about partners of those pregnant women. There is also a discussion, because (inaudible) well CMV, you go down in (inaudible) CMV so there is a lot of different segments that we will discuss quite at length on the R&D Day. But this is why I think we believe CMV -- if you take a (inaudible) time-frame from and if you look at all of your vaccines, like the HPV vaccine and the best vaccine in those very important vaccines.

The lifecycle management of those products can be very important, and we have our eyes, very much on how do we go about this, again, we cannot all indication at the same time is going back to the discipline on capital allocation and investments. But we are very much in line of how do we maximize of plan this opportunity to get the largest labor that we can for CMV. So it can be given towards the largest population we can around the world not only in the US.

Q - Jennifer {BIO 1827328 <GO>}

Thank you so much. And the other question is for the hMPV/PIV3 vaccine. Could you possibly give us some comments or color or any new understanding of the tighter level needed to progress this effort. Thank you.

A - Tal Zaks {BIO 19987702 <GO>}

This is, Tal. I think that our understanding of the titers there is going to be based mostly on the preclinical modeling and what we've seen to date that is protective. Unfortunately there is no vaccine on the market. So we don't really have a correlate of protection like we have some influenza. But it is a respiratory virus. So one draws similar parallels from the

experience with flu. And you get a sense from the totality of our understanding in the science on the respiratory viruses, what are the titers like. I think what we've seen in the Phase 1 is supportive of our ability to immunize recall though that the target population here is in zero negative infants.

Right. So ultimately, we're going to have to define our ability to reach significant titers and boost to the maximal of the immune response capability to respond in that population down the road. So I think it may not be a very black and white answer, because I think -- it will take influence from multiple lines of reasoning from science and from clinical studies in from other vaccines. I think to come to that. Does that help you?

Q - Jennifer {BIO 1827328 <GO>}

Yes, thank you so much for taking my questions.

Operator

Our next question comes from Hartaj Singh of Oppenheimer & Company. Your line is open.

Q - Hartaj Singh {BIO 18796450 <GO>}

Great. Thank you for the questions. I just have two. One is, I know that you've mentioned that the check antibody is very important. Can you just talk maybe a little bit about that. If you see the proof-of-concept manufacturing the antibody, we're using mRNA and then see efficacy on the vaccine side. Antibodies are over $100 billion in sales priority. What other areas could you go into, would you see yourself being in vaccines call there other type of antibody other types of diseases that be amenable to your approach in that regards or is that just looking too far into the future. And then I've got a quick follow up.

A - Stephane Bancel {BIO 15174250 <GO>}

So good morning. It's Stephane. So, as you know, we have disclose of 21 development candidates and we don't comment on future planning research. Obviously, as I said in my remarks, we've been -- it's a very important milestone. It's a first time that's using a modern technology. An antibody is being produced in human. And so, that's an important technology that as you commented as a lot of the front applications.

What we try to do always as the portfolio of the assets that we develop we will show us capital is to be both managing biology risk, technology risk and to create important innovative products for patients. As always, a big driver for us. If you look back to one of my closing slide, if you look at the portfolio through the fall, most of the products of 5 plan base has no product on the market the big enough medical need and there is no solution in the market. And so we are always put about all those things but it would be, of course, become a very important tool in our Moderna toolbox. As you know, partnering is also an important possible strategy, if you go back over time done full partnership with Merck. If we were very -- we are very, of course, happy with the decision by the FX to expand the collaboration. And so that is of technology it can be make available to partner. So this is an important piece of IL-12 box.

Q - Hartaj Singh {BIO 18796450 <GO>}

Great. And that's helps a lot. And then just I had a quick question on your manufacturing strategy, I mean, I visited the Norwood facility. Really, really kind of cool stuff going on there, it is clinical grade sort of material and research material. Can you just talk a little bit about how you're thinking about your commercial grade material. I mean you're getting to the point now where you might have one or two whether rare or diseases where you might be able to get to the clinic fairly rapidly and the regulators want to see of the clinical to commercials sort of strategy. Can you just talk a little bit about that, and then which of your modalities actually requires more intensity from a commercial manufacturing perspective than others. Thank you.

A - Stephane Bancel {BIO 15174250 <GO>}

It's a great question. So on the commercial front as we've shared in the past, Norwood is able to do commercial, he is not ready to there, would have to do much work on validation and quality systems and so on. But the infrastructure of the plant itself has been build, so that the site can be brought to commercial readiness and being able to do pivotal studies, restriction studies out of Norwood. What we also shared and it's again going back to all focus on managing the risk, we will not have to be the commercial facility before we have our first commercial product approved, that's a very important part of more than our strategy to de-risk the company. So we cannot product that of Norwood, we can do Phase III up of Norwood. We will get the fact -- on-time so that we can do that. We are also always have a contract manufacturer strategy, we never want to be single source for the company. That would be with risky. So we have as we speak contract manufacturer that capital so commercial capabilities from their sites and the quality system ready.

And if you think about the different product on portfolio, which is a second question. The big impact is mostly on the back end, which is around filling device because if you think about mRNA for Vaccines the those up very, very tiny. So you don't need a lot of mRNA drug substance to supply chain millions of ICE, because if you go back to the data we have published or vaccines (inaudible) in the 2,500 microgram per human. So in (inaudible) we can do a lot of those that can do the math, and so and already, because at the end of patients is low USO [ph] don't go into gigantic quantities, of course, in oncology a different ballgame. But again, that would be very happy program to manage, when we get there on the back end.

Now it does not have the ability to do millions of wiser feelings with that's something that is readily available for contract manufacturing. So that is why we would feel very confident that we have the -- we've applied infrastructure that we have the ability to do pivotal to the commercial, if we have to manage the back end we've Norwood capacity we will get and contract that out. We've been a distinct partner or new partner, we have time for that. And if we needed more capacity, one thing to remember about Norwood is that we can increase the capacity of Norwood tremendously us use the current capacity.

We are only working with two day shift, we could put of course a night shift. We don't have shift on weekend. So right there you have a lot of capacity available, we can move a warehouse out of the site. The warehouse doesn't have to be on the site. And you have

right away more GMP facilities that you can access your utilities. The QC lab can also be moved up of our planet can be moved on the parking lots you just be then you're building and here again, you go with more GMP capacity, the preclinical robotics opportunistic or something is currently in GMP's risk but doesn't have to be, because it's preclinical material.

So yeah, again, you can move into the parking lot on the new building. So if you think about the manufacturing strategy of Moderna, not with us a big investment, we think it's a strategic investment, we cannot deliver on the mission of the company all the pipeline growth Norwood. But we will it be Norwood, so this becomes the central not for us that is definitely a very long-term, so that we do not have to invest capex in the years to come as a high-level will not be the commercial plant and tubular product that would be way too risky.

Q - Hartaj Singh {BIO 18796450 <GO>}

Great. Thank you, sir, and that's great.

Operator

Our next question comes from Alex (inaudible) of Bank of America Merrill Lynch. Your line is open.

Q - Unidentified Participant

Hey guys, thanks for taking my questions and congrats on the progress. I just had a couple. So, maybe first on the hMPV PIV3 combination vaccine. Do you have a sense of the sort of data will likely see in October and will we see data outside of antibody titer comparison. And is the Phase 1B a toddler study necessary for your conversations with the FDA before you begin to Phase 3, and then I have one more.

A - Stephane Bancel {BIO 15174250 <GO>}

Thanks, Alex. It's Tal. So in October we will present the totality of the data as we have it. So you will see the antibody titers you'll see the total of the safety, you'll see, would you typically see when we describe it to tell in the study. And I believe that's been accepted to ID week. In terms of the sheer positive toddlers. Yes, I think that is consistent with the development path that one would expect and that the agency concurs in terms of the next step in the development path here. So ultimately, remember that the target population here as infants. So there is a pretty structured and rigorous way by which you work your way down into that population.

Q - Unidentified Participant

Okay. Great.

A - Tal Zaks {BIO 19987702 <GO>}

Given the sensitivity to the pediatric population. We wanted to make sure that we've got clarity from the agency in terms of deciding that study, and that's why we put in the press

release and we discussed that interaction.

Q - Unidentified Participant

Right, right, I understand that the sensitive on patient population. And then shifting gears to your KRAS vaccine 5671, we've seen data from Amgen and others that are pretty encouraging and G12C although it seems maybe there is a subgroup that requires additional combination therapies. So I was just curious on the KRAS being what your thoughts are for it as monotherapy, and also in terms of combination with checkpoint inhibitors. Thanks.

A - Tal Zaks {BIO 19987702 <GO>}

Yeah. So I'll give you two versions of the answer. One of the signs and one is the drug developer. On the signs unquestionably one would want to combine these as early as possible because we think there is Orthogonal as I described previously, and one would expect these get combined with checkpoint inhibitors. In addition, as a drug developer, you want to get confidence first that you're -- that each individual has merit on its own before you go into the combination. I think for us it's critical to demonstrate that the cancer vaccine as such in combination with the PD-1 inhibitor can actually immediate responses. I think once we get to that stage we will obviously have a keen interest in pursuing the right combinations with the inhibitors depending on where they are at that point in time.

A - Stephane Bancel {BIO 15174250 <GO>}

Alex, did that answer your question?

Q - Unidentified Participant

Yes, that's great. Thank you.

Operator

There are no further questions, I'd like to turn the call back over to Stephane Bancel for any closing remarks.

A - Stephane Bancel {BIO 15174250 <GO>}

Thank you for joining us today for your questions. We look forward to hosting you during off upcoming filled annual R&D Day in New York City. This meeting will be held during the morning of September 12. Have a wonderful day. Thank you.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program, and you may all disconnect. Everyone have a great day.