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PRESENTATION

Operator

Good morning, and welcome to Moderna's Second Quarter 2019 Conference Call. (Operator Instructions) Please be advised that the call is being recorded. At this time, I'd like to turn the call over to Lavina Talukdar, Head Investor Relations at Moderna. Please proceed.

Lavina Talukdar - *Moderna, Inc. - Head of IR*

Thank you, operator. Good morning, and welcome to Moderna's second quarter 2019 conference call to discuss business update and financial results. You can access the press release issued this morning as well as the slides that we'll be reviewing by going to the Investors section of our website at www.modernatx.com.

Today, on this call, we have Stéphane 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 Stéphane.

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

Thank you, Lavina, and good morning, everyone.

We believe that mRNA has the 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 timelines 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 protein and that our manufacturing cost at commercial scale will be similar to small molecule injectable. Because of this large potential, we continue to focus on managing the 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 derisk a sentinel program, they are important breakthroughs. As a key, therefore, 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 3 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 projected positive interim Phase I data at the ASCO meeting in June and since, we are happy to report today that since ASCO, we started a Phase II 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 are happy to report today that the Phase I for CMV has completed and in all healthy subject at doses up to 300 microgram. We believe CMV is a large unmet medical need, and we look forward to reviewing and showing the Phase I trial data in the near term.

The team continued to execute at a rapid pace in the last 90 days. We advanced 4 new programs into Phase I since our May quarter. Two programs in immuno-oncology started dosing cancer patients. Our KRAS vaccine, which is partnered with Merck, and the IL12 intratumor, which is partnered with AstraZeneca [dosed the first patients]. 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 U.S. agency, BARDA.

Finally, I am happy to report that clinical sites are now open and actively recruiting patients in our first rare disease program, MMA. We have 3 open sites in the U.S. And in the U.K., the clinical trial application, or CTA, was just opened by local authorities.

I am very pleased with the company's progress and I am very thankful for the team dedication to this execution. We now have 5 immuno-oncology programs in the clinic, including PCV in Phase II and OX40 soon entering Phase II. We have 5 important rare disease program and are still working out to dose the first MMA patient and to submit INDs for all our rare disease programs. We have 4 vaccines in the clinic for major unmet medical needs; CMV, RSV, the hMPV+ PIV (sic) [hMPV+ PIV3] combo and Zika.

I want to remind you that there are no approved vaccines for any of these harmful pathogens that similarly affect thousands each year. We are very pleased to have completed enrollment in our CMV trial and we look forward to sharing the data with you soon. 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 - *Moderna, Inc. - Chief Medical Officer*

Thank you, Stéphane.

As you know, we're advancing our pipeline of medicines in 6 different modalities. In the next few slides, I will highlight the progress we've made this quarter in each of these.

So starting with prophylactic vaccines on Slide 13. You will see we have 8 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 I study 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 I trial, and I'll go over this opportunity in greater detail in just a moment.

The RSV Phase I 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, had just filed the IND.

Our Zika program with mRNA-1893 also had the IND filed and opened in the second quarter, and I'm happy to report that the first subjects on the Zika Phase I trial was also dosed.

In terms of emerging data, in hMPV+ PIV3, or mRNA-1653, we continue to see neutralization titers above baseline at the second interim look, 7 months after the last vaccination. For context, in January, we reported the 2-month immunogenicity data. We plan to present the full data from this Phase I study at IDWeek in the fall.

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

Finally, the Phase I data for influenza vaccines against age 7 and age 10 were published in the Journal of Vaccine.

Let me know spend a few minutes on CMV.

As noted, before the Phase I 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 where approximately 25,000 newborns are infected each year in the U.S. alone. Currently, there aren't any vaccines against the CMV virus on the market. That's because CMV is proving to be a challenging vaccine to manufacture using traditional technologies given the structure of one of the antigens, the pentamer, which we think is required to elicit a protective immune response. We believe these challenges can be overcome with our mRNA vaccine as our technology lends itself to producing the pentameric viral antigen by encoding for the simultaneous translation of its 5 components.

As a reminder, and as shown on Slide 15, mRNA-1647 actually contains 6 mRNA sequences, 5 of which encode for this pentamer and 1 that encodes for the gB protein. We believe the combination of these 2 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 I 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, our personalized cancer vaccine, and on the KRAS vaccine, mRNA-5671. Recall that we and our partner, Merck, announced the Phase II trial earlier this year. The Phase II design is a randomized trial testing the combination of mRNA-4157 in combination with pembrolizumab against the pembrolizumab monotherapy control arm in high-risk melanoma patients in the adjuvant setting. I'm happy to report today that the Phase II is up and running and that the first patients have consented to the trial. Interim safety tolerability and immunogenicity data from our Phase I were the basis for the decision to move to Phase II. We presented these interim data with mRNA-4157 either as monotherapy in a resected adjuvant population or in combination with pembrolizumab in the metastatic setting. These 2 arms represent arms A and arms B, respectively of the Phase I study. We have a part C and part D that continue to enroll. Our [T] histologies include microsatellite 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've 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 neoantigen-specific T cell activation in 10 of the 18 Class I neoantigens and the 1 patient treated at a 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 now 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 the both the Phase I and Phase II studies have been receiving the 34 neoantigen version. At ASCO, while the clinical data are early and preliminary, we did report 6 responses in part B of the study in the metastatic setting. One of these was a complete responder to pembrolizumab monotherapy prior to receiving the personalized cancer vaccine and 5 other dosed with the combination of mRNA-4157 and pembrolizumab had a partial response. 2 of these 5 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 II 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 I trial testing KRAS vaccine mRNA-5671 was dosed. As a reminder, KRAS is a key regulator of cell proliferation and survival. Mutation in the KRAS gene cause disregulated 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 cancers, 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 a mutated KRAS epitope by T cells can lead to cancer [regression].

A quick overview of mRNA-5671 is shown on Slide 21. It encodes for the 4 most prevalent mutations of KRAS, which together represent 80% to 90% of KRAS mutations. The genetic sequences that span the mutations are combined into a single mRNA that encodes for all 4 neoantigens. When translated within the cell and to a neoantigen protein chain, the cellular [protozonal] machinery is expected to clear the chain and present these neoantigens to the immune system to stimulate what we hope will be an active anticancer T cell response. The Phase I trial for this vaccine, which is being run by our partner, Merck, has enrolled its first patient, and the 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 designs are most likely to respond.

For the intratumoral immuno-oncology programs, we are progressing with all 3 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 I is completing the dose confirmation cohort at 8 milligram and in parallel we're progressing to start the Phase II cohort in patients with advanced ovarian cancer.

Slide 26 shows a schematic of the Phase I trial and the Phase II cohort.

Turning to mRNA-2752, or the Triplet, which encodes for OX40 ligand and 2 proinflammatory cytokines, interleukin 23 and interleukin 36 gamma. The rationale here was to stimulate T cells through the presence of OX40 ligand while attracting the T cells to the tumor site with the local expression of these cytokines. By injecting the tumors directly, we expect the cytokines to act locally within the tumor microenvironment. The Phase I is ongoing and has both the monotherapy arm and a combination arm with durvalumab. I'm pleased to report that the first patient in the combination arm with durvalumab has been dosed.

We've also made progress with MEDI1191 in our interleukin 12 intratumor injection program, partnered with AstraZeneca, as the first patient in this trial was dosed. Recall that interleukin 12 is a potent immunomodulators 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 being administered systemically. We believe that the intratumoral mRNA approach should allow for interleukin 12 to act locally in the tumor microenvironment while avoiding the toxicity seen with systemic administration.

Let me touch for a moment on the localized regenerative therapeutics and AZD801 (sic) [AZD8601]. The Phase IIa in coronary arterial bypass graft population is ongoing. Our partner, AstraZeneca, continues to open additional sites in Europe with a clinical trial application now 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 6 of the 8 subjects in the third dose cohort. Before I get to the trial design and the strategy among this program, I 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

a complex protein that require both a heavy and a light chain to come together to form an active protein. So mRNA-1944 actually includes 2 mRNAs, one that encodes for heavy chain and one that encodes for the light chain. Once formed, we expect the antibody to be secreted into the bloodstream where we will be watching to see if it confers passive immunity against the chikungunya virus as expected.

On Slide 36, you will see the trial design. The key objectives of the trial are to evaluate the safety and tolerability of 4 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.

Now the utility of this program is really twofold. 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 4 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 are inborn errors of protein metabolism that are caused by mute enzyme deficiency and PCC deficiency, respectively. As you can see, these 2 acidemias are really on the same metabolic pathway. Now the prevalence of both is approximately 325 to 2,000 patients in the U.S. Patients are identified during newborn screening and current regimens are palliatives; 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 and mRNA-3927 encode 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 2 programs for rare pediatric disease vouchers. The Phase I study of our sentinel rare disease program in MMA with mRNA-3704 currently has 3 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 both 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 H. Kim - *Moderna, Inc. - CFO*

Thanks, Tal. In today's press release, we reported our second quarter 2019 financial results. Please note these results are unaudited.

We ended Q2 2019 with cash, cash equivalents and investments of $1.44 billion. This compares to $1.69 billion at the end of 2018. We are reiterating today our expectation for cash, cash flows 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 6 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 stated in the footnote. After the first quarter of 2019, we have no further in-licensing payment obligations to Cellscript and its affiliates. Cash used for purchases of property and equipment was $18 million in the first 6 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 ASC606 using the modified retrospective transition method applied to these contracts which were not completed as of January 1, 2019.

The decrease in total revenue for Q2 on the first 6 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 6 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 6 months of 2019.

R&D expenses for Q2 2019 were approximately $128 million compared to $104 million for Q2 2018. And for the first 6 months of 2019, R&D expenses were $259 million compared to $195 million in 2018. The increases in Q2 and the first 6 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 of 2018. And for the first 6 months of 2019, G&A expenses were $56 million compared to $38 million in 2018. The increases in Q2 and the first 6 months of 2019 as compared to 2018 were mainly due to the additional costs 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 Stéphane.

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

Thank you, Lorence.

To close our remarks, I would like to reiterate that our team is focused on executing on 3 priorities: advancing the development pipeline, investing in new development candidates in the existing 6 modalities and [investing] in new modalities. The team at Moderna executed across the board during the quarter.

To summarize quickly the highlights of the quarter. We initiated the PCV Phase II trial with first patients consenting to participate in the trial. Our CMV vaccine study is fully enrolled. We started 4 new clinical trials, 2 in immuno-oncology and 2 in infectious disease. Vertex cystic fibrosis 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 today, Vertex has extended this collaboration for 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 today and look forward to the rest of 2019 and 2020 as we approach critical data readout. I will particularly look for the CMV Phase I data and the chikungunya antibody Phase I 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 both] in healthy subject, these trials should complete soon and if positive, we intend to transition to Phase II. We now have 5 immuno-oncology programs in the clinic, 2 of which are already building in combination with approved checkpoint inhibitors, Merck's KEYTRUDA for PCV and AstraZeneca IMFINZI for Triplet. Our teams working with clinical trial sites are focused on the milestone of dosing of first patients with MMA. We believe mRNA has the potential to be a new class of medicine. We see a large product opportunity ahead of us and we are energized by the potential to bring these important medicines to patients. Four vaccines for large unmet medical needs where there is no vaccines approved today. That is a unique opportunity, to help millions and as such, create large commercial products. Five immuno-oncology programs, which all have the potential to improve the response of PD-1 or PD-L1 checkpoint inhibitors. Five are disease programs for conditions like MMA and PA where [children's bond with the] detected protein urgently need the treatment [that targets] the underlying cause of their disease. The cardiology program, VEGF, which could transform the care of patients with severe (inaudible).

And it's only the first wave of innovative products. Stephen Hoge and his team are working hard to move new innovative development candidates from the labs, into the clinic. The productivity of our mRNA platform is significant. We built our first clinical trial in December 2015. In just 3.5 years, we started 16 programs in the clinic and we have had a high success rate. The team did get 19 IND off CTAs opened 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 to patients.

I would like to end our remarks by thanking the many people who participate in our clinical studies, including patients, healthy volunteers and physicians. I would also like to thank the great team of Moderna employees working hard every day 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 with Goldman Sachs.

Andrea R. Tan - *Goldman Sachs Group Inc., Research Division - Research Analyst*

This is Andrea on for Salveen. My first one is how are you thinking about positioning for your KRAS vaccine in the context of growing competition in this space? And then I have a follow-up.

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

This is Tal. Look, first of all, I'm 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 2 points. First, the exact nature of the activity and against which mutations and in our case, which mutations and which HLA 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 has translated into real benefit for these patients. But we've struggled to turn them into [curative] 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 I'm -- yes, I'm really excited in the coming years to see how that story plays out.

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

And let me -- Stéphane -- just to add one thing. As Tal described in his remarks, the mRNA that we designed is actually coding for 4 mutations G12D, G12V, G13D and G12C.

Andrea R. Tan - *Goldman Sachs Group Inc., Research Division - Research Analyst*

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

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

So in the clinical study, we have not yet enrolled. We're actively recruiting. In the natural history study, there have been 71 patients enrolled to date.

Andrea R. Tan - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Sorry. Do you anticipate, I guess, rolling any patients over from that national natural history study or not?

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

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

Operator

Our next question comes from Matthew Harrison of Morgan Stanley.

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

Two for 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 the third cohort? I don't know if you can comment on what the stopping rules are from a safety standpoint. And then a second question is on OX40 ligand. Can you talk about what do you need to do in this Phase II study to be able to take back to the FDA -- I mean, I guess what I'm asking is how should we think about potential regulatory path forward with that molecule?

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

Sure. Look, 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 study so 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 are expanding into the Phase II cohort, we are 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 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?

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

It did. Thank you.

Operator

Our next question comes from Ted Tenthoff with Piper Jaffray.

Edward Andrew Tenthoff - *Piper Jaffray Companies, Research Division - MD & Senior Research Analyst*

So my question is -- and I apologize if this was asked, but with respect to the Triplet, my concern here is to certainly not activity, especially with durvalumab, but are you doing any special immune safety analysis or any special additional safety analysis just because of the potential potency of the Triplet therapy?

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

Thanks, Ted. That's a really good question and I wish 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, maybe 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 phenomena, et cetera, and all the other adverse events that one would expect from checkpoint inhibitor monotherapy. And assessing very carefully to see whether we exceed it.

If there's any other safety signal that is attributable to the Triplet, then I think we've got 2 ways of finding it. First, recall we are 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 as 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 maintain a careful vigil for what's expected and make sure you're not missing anything unexpected. I don't know if that answers the question. I'm not sure I've got a better one.

Edward Andrew Tenthoff - *Piper Jaffray Companies, Research Division - MD & Senior Research Analyst*

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 mean] not just treating lung but really systemic disease?

Stephen Hoge - *Moderna, Inc. - President*

It's Stephen Hoge. So first of all, it's a research collaboration with Vertex and we're excited to continue it based on 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 1 direction here but we haven't yet defined a development candidate. At which point, we would probably provide specifics about that. Generally our approach with Vertex in CF has been to address the unmet needs in CF, particularly for those patients who [have all of those needs] -- for CFTR and focusing intensively on the pulmonary disease. But obviously without commenting specifically in the CF example, pulmonary delivery is a route of administration that could be valid for other systemic diseases or other applications as well.

Operator

Our next question comes from Cory Kasimov of JPMorgan.

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

I have 2 as well. So I guess, first, can you just 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? I think -- beyond the CMV and chikungunya update, what else has a chance of occurring in that time period? And will we see new clinical data at your R&D day in September? And then I have one follow-up.

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

It's Stéphane. So I will not comment on the R&D day. I hope you come to the R&D Day. We will make sure that we give a good update on everything we know then. 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 really think it's a very large opportunity. We own 100% of the economic of this product. We believe there's a very large medical need out there. And so the CMV data are going to be very important, we believe, for the company.

RSV and Zika, because they are in Phase I in healthy subjects and they are dosing as we speak should [ready] pretty quickly. And that as I shared, the plan is to move those to Phase II, assuming we have good data into the clinic. I'll remind you that we have already in the past shown [in a good translation] from primate into humans into [our vaccine have had] positive data. And so we look forward to this data in humans.

PCV, of course, will take a little bit of time because we started a Phase II, that's a very important study. We need to recruit for that Phase II, [in all] 150 patients across the board. And then it's -- it's, of course, looking at survival in 12 months.

KRAS is going to be interesting. We all believe there's a big medical need (inaudible) tumor types. So we have [therapy] [in 2] patients in Phase I so we will be sharing observation at the planned clinical meetings of what we see in the clinic.

In the intratumoral, because it's oncology and we are dosing -- we prepared it in combination with PD-1 -- OX40 will be in Phase II soon. And also, it will be in combination with a checkpoint. (inaudible) IL12. Forward -- same thing. We will update at different medical meetings all the clinical observations [except as recruiting]. And then as we discussed, the CHIK antibody is very important for us. And then getting the first [results] in the clinic. The (inaudible) are going to go straight into patients. As we commented before, we are starting MMA at a dose that has been shown in animal models having some benefit. And so I think the next few months and the next few quarters are going to quite rich, data-wise. We have now (inaudible) testing drugs [for launching] in the clinic. That's a lot of potential data we have.

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

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 of high risk of relapse or PD-1 refractory? And what do you see as the potential of this program in indications that have -- that might have considerably less [neo appetites]?

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

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 in 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 I and that's why we went into an adjuvant setting even within melanoma for a definitive study to Phase II. I think once we have a clear proof of concept, clearly, we will begin to explore some of those additional indications. But there's not any current plans to do that.

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

And Cory, it's Stéphane. To add to Tal's remarks, if you think about it, going back to Lorence's comments, we are very disciplined with capital allocation. So, of course, there could be a lot of different things one could think of trying with personalized cancer vaccine. As you think of it, all the patients [that benefited] today. But unfortunately, we cannot [know] -- before we have an important [derisking], we cannot expand too much because we have so many opportunities of products across our portfolio, we could be increasing the burn to a place that will not be reasonable. And so we want to be very disciplined. And I -- just one example, but there's a lot of things, trust me, that the clinical team -- as you know, Tal is an oncologist by training, who loves to be trying in the clinic to help those patients. But we just have to be very disciplined with capital allocation and how much we spend and where we spend it and when we spend it based on derisking.

Operator

Our next question comes from Alan Carr of Needham.

Jennifer Shen - *Needham & Company, LLC, Research Division - Research Analyst*

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

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

So thank you, Jennifer, for the question. I think it would be great if you can join us at 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, adolescent women that you might want to protect, there is a discussion about partners of those pregnant women. There is also a discussion because humans are very (inaudible) CMV, do you put down an age to try to eradicate CMV? So there's 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 10, 20 year time frame. And if you look at the [all the other] vaccines, like the HPV vaccine and the (inaudible) vaccine, 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 do all the indications at the same time. It's going back to discipline on capital allocation and investment. But we have very much in mind of how do we maximize [the time] this opportunity to get the largest label that we can for CMV so it can be given to the largest population we can around the world not only in the U.S.

Jennifer Shen - *Needham & Company, LLC, Research Division - Research Analyst*

And the other question is for the hMPV/PIV3 vaccine, could you possibly give us some comments or color on any new understanding of the titer level needed to progress this asset?

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

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 protected. Unfortunately, there is no vaccine on the market so we don't really have a correlate of protection like we have from 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 and the science on the respiratory virus as what are the titers like. I think what we've seen in the Phase I is supportive of our ability to immunize. Recall though that the target population here is in seronegative infants, right? So ultimately, we're going to have to define our ability to reach significant titers and boost to the maximal 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 inference from multiple lines of reasoning from science and from clinical studies and from other vaccines, I think, to come to that. Does that help you?

Jennifer Shen - *Needham & Company, LLC, Research Division - Research Analyst*

Yes. Thank you.

Operator

Our next question comes from Hartaj Singh of Oppenheimer & Co.

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

Great. I just have 2. One is, I know that you've mentioned that the CHIK antibodies is very important. Can you just talk maybe a little bit about then if you see the proof of concept -- you know, manufacturing the antibodies using mRNA and then see efficacy on the vaccine side -- antibodies are over $100 billion in sales per year. I mean what other areas could you go into? Would you see yourself being in vaccines? Are there other types of

antibodies, other types of diseases that would be amenable to your approach in that regard? Or is that just looking too far into the future? And then I've got a quick follow-up.

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

So good morning, it's Stéphane. So as you know, we have disclosed 21 development candidates and we don't comment on future plans and research. Obviously, as I said in my remarks, we think it's a very important milestone. It's the first time that using mRNA technology, an antibody is being produced in a human. And so that's an important technology that, as you commented, has a lot of different applications. What we try to do always as the portfolio of the asset that we develop with our shareholder's capital is to be thoughtful about managing biology risk, technology risk and to create important, innovative products for patients. That's always a big driver for us. If you look back to one of my closing slides, if you look at our portfolio today, for most of the products we have in the pipeline, there is no product on the market that's bigger [than the medical] need and there is no solution in the market. And so we're always thoughtful about 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 part of our strategy. If you go back over time, we've done 4 partnerships with Merck, (inaudible). We are very, of course, happy with the decision by Vertex to expand their collaboration. And so that's also -- technology can be made available to a partner. So this is an important piece in the Moderna toolbox.

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

Great. That helps a lot. And then I just had a 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 1 or 2 other rare or diseases where you might be able to get to the clinic very rapidly and the regulators want to see it [as a sort of] clinical to commercial 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?

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

That's a great question. So on the commercial front, as we've shared in the past, Norwood is able to do commercial. It's not ready today. We have to do much work on validation and the quality systems and so on. But the infrastructure of the plant itself has been built so that the site can be brought to commercial readiness and being able to do pivotal studies, registration studies out of Norwood. What we also shared and it's again going back to our 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 Moderna strategy to derisk the company. So we cannot produce out of Norwood. We can do Phase III out of Norwood. We will get the facts ready 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 will be way too risky. So we have, as we speak, contract manufacturers that have also commercial capabilities from their site and the quality system ready.

And if you think about the different products on the portfolio, which is the second question, the big impact is mostly on the backend, which is on filling device. Because if you think about it, mRNA for vaccines, the dose are very, very tiny so you don't need a lot of mRNA drug substance to supply actually millions of vials because if you go back to the data we have published, our vaccines show efficacy in the 2,500 microgram type per human -- so [in procure] we can do a lot of -- doses per [liters] you can do the math. And so, and [for the record] this is because the n of patients is low, you also don't go into gigantic quantities. But of course, oncology, it's a different ballgame. But again, that will be a very happy program to manage when we get there.

On the backend, Norwood does not have the ability to do millions of vials of fillings. But that is something that is [realizable] through contract manufacturing. So that is why we feel very confident that we have the -- with the current infrastructure that we have, we have the ability to do pivotal, to do commercial. If we have to manage the backend with more vial capacity, we will get and contract that out with an existing partner or a new partner, we have planned for that.

And if we needed more capacity, one thing to remember about Norwood is that we can increase the capacity of Norwood tremendously versus the current capacity. We are only working with 2 day shifts. We could put, course, a night shift. We don't have a shift on weekends. So right there you have a lot of capacity available. We can move the warehouse out of the site. The warehouse doesn't have to be on the site -- and you have, by the way, more GMP facilities that you can access your utilities. The QC lab can also be moved out of the plant. It can be moved on the parking lot -- you just build a new building. And here again, you go with more GMP capacity. The -- [pre-clinical], all the robotics are [pre-clinical.] Same thing. It's currently in a GMP [Swift] but doesn't have to be, because it's pre-clinical material. So there again, you can move it to the parking lot on your new building.

So if you think about the manufacturing strategy of Moderna, Norwood was a big investment, we think it's a strategic investment. We cannot deliver on the mission of the company or the pipeline without Norwood. But we really built Norwood so that this becomes the [central knot] for us, that is there for a very long term so that we don't have to invest CapEx in the years to come at the high-level. We will not build a commercial plant until we are product-approved. That would be way too risky.

Operator

Our next question comes from Alec Stranahan from Bank of America Merrill Lynch.

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

I just had a couple. So maybe first on the hMPV/PIV3 combination vaccine. Do you have a sense of the sort of data we'll likely see in October? And will we see data outside of the antibody titer comparison? And is the Phase Ib toddler study necessary, as per your conversations with the FDA, before you begin a Phase III? And then I have one more.

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

Thanks, Alec. This is Tal. So in October, we'll present the totality of the data as we have it. So you will see the antibody titers, you will see the total of the safety, you'll see what you typically see when we describe the totality of the study. And, I believe that's been accepted to IDWeek.

In terms of the seropositive 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 is infants. So there is a pretty structured and rigorous way by which you work your way down into that population. Now given the sensitivity to the pediatric population, we wanted to make sure that we've got clarity from the agency in terms of designing that study, and that's why we put it in the press release and we discussed that interaction.

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

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

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

So I'll give you 2 versions of the answer, one on the science and one as a drug developer. On the science, unquestionably, one would want to combine these as early as possible because we think there's orthogonal benefit, as I described previously. And one would expect that it gets combined with checkpoint inhibitors in addition.

As a drug developer, you want to get confidence first that your -- 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 a PD-1 inhibitor can actually mediate 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. Alec, did that answer your question?

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

It did. Thank you.

Operator

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

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

Thank you for joining us today, for your questions. We look forward to hosting you during our upcoming third 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.
