Q3 2020 Earnings Call

Company Participants

- David Meline, Chief Financial Officer
- Lavina Talukdar, Head Investor Relations
- Stephane Bancel, Chief Executive Officer
- Stephen Hoge, President
- Tal Zaks, Chief Medical Officer

Other Participants

- Alan Carr, Analyst
- Cory Kasimov, Analyst
- Edward Tenthoff, Analyst
- Gena Wang, Analyst
- Geoff Meacham, Analyst
- George Farmer, Analyst
- Hartaj Singh, Analyst
- Mani Foroohar, Analyst
- Matthew Harrison, Analuyst
- Michael Yee, Analyst
- Navin Jacob, Analyst
- Salveen Richter, Analyst
- Umer Raffat, Analyst

Presentation

Operator

Good morning and welcome to Moderna's Conference Call. At this time, all participants are in a listen-only mode. Following the formal remarks, we will open up the call for your questions. Please be advised that the call is being recorded. At this time, I'd now turn the call over to Lavina Talukdar, Head-Investor Relations at Moderna. Please proceed.

Lavina Talukdar {BIO 19691239 <GO>}

Thank you. Good morning everyone and welcome to Moderna's Third Quarter 2020 Conference Call to discuss financial results and business updates. 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. On today's call are Stephane Bancel, our Chief Executive Officer; Tal Zaks, our Chief Medical Officer; Stephen Hoge, our President; and

David Meline, our Chief Financial Officer. Before we begin, please note that this conference call will include forward-looking statements made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995.

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 revise the information or provide -- 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. Good morning or good afternoon everyone. I hope all of you and your loved ones are in good health and remain safe. Thank you for joining our Q3 business update conference call. I will start with reviewing key highlights. I would like to focus on three topics, first our COVID-19 vaccine, second our broader development pipeline, and finally key financials. As many of you know, we completed enrollment of our Phase 3 COVE Study for mRNA-1273. 30,000 participants have been enrolled in the study, 37% of whom are from diverse communities. Tal will give you some details in a few minutes. We are grateful for the participants in the study and for our principal investigators. I would like to also thank PPD and NIH for a great job and collaboration.

It is very important to the Moderna team that we have a high bar for quality and transparency to ensure [ph]the public has trust in COVID-19 vaccine. We have reported weekly enrollment progress of our COVE Study and have reported weekly enrollment numbers from diverse communities. When we were not happy with the representation of these diverse communities given the high burden of disease in these populations, we decided to slow down the overall COVE Study enrollment process in order to recruit more people from diverse communities. As you can imagine, it was not an easy decision to slow down, but it was the right decision.

We signed the biopharma pledge to not submit for regulatory approval for mRNA-1273 until we have adequate safety and efficacy data. We were also the first company to file the full, unredacted [ph]version of our Phase 3 protocol online to ensure clinicians around the world could see in full transparency how the COVE Study is being run.

We were pleased to set the [ph]standard and (inaudible) in the industry for the audit. We continue to expect our first interim analysis to readout in November. The Independent Data Safety Monitoring Board or DSMB will carry out these interim analyses and then inform Moderna. We should have a [ph]passed second dose two-month safety follow-up after the second vaccination of 15,000 [ph]median participants in the second half of November.

As many of you know, this is what the USFDA has asked as part of a EUA submission in the latest guideline published ahead of the October 22 VRBPAC meeting. We are working closely with USFDA to file Chemistry, Manufacturing, and Control or CMC components as soon as they are available to ensure CMC is not on the critical path to an EUA approval.

In addition to the ongoing dialog with USFDA, we have announced rolling submissions for mRNA-1273 in the UK and Canada and received confirmation of eligibility for submission of marketing authorization application to the EMA for the EU.

We are very pleased to announce this morning that we have signed a partnership with -- in Japan with Takeda for an order of 50 million doses for the Ministry of Health, Labor and Welfare of Japan. In the third quarter, we have received $1.1 billion of cash payments from governments around the world and those are accounted in our financials as deferred revenues.

Let me now turn to our broader pipeline. We announced at the R&D Day in September the positive Phase 2 readout for mRNA-1647, our CMV vaccine. We are on track to start the pivotal Phase 3 registration study for CMV in 2021. I would refer you to our April Vaccines Day presentation in which were communicated that we believe our CMV vaccine has a potential for annual peak sales between $2 billion and $5 billion dollars. There is no approved vaccines against CMV and it is the number one cause of [ph]drug defect in the US and the developed world. Moderna owns the global rights to CMV 1647.

Our intratumoral OX40 ligand program that many of you had heard about at our recent R&D Day (inaudible) patients in the Phase 2 expansion study. In rare disease, startup activities and (inaudible) protocol for Phase 1 propionic acidemia or PA study are underway. All of our pipeline programs that we're enrolling and dosing patients is to continue and ongoing.

Let me finish this slide with a few words about financials. David will go through the financial numbers in a few minutes, but I wanted to share a few thoughts. As I mentioned earlier, we reported this morning that we booked $1.1 billion of deferred revenues in Q3 for supply agreements for mRNA-1273. This cash has been received by the Company.

These cash receipts have enabled the Company to generate $893 million of cash flow provided by operating activities in the third quarter after investments of approximately $300 million in the business.

If you turn to slide 4, I am pleased to report that this is a first quarter in the Company's history in which we reported positive cash flow provided by operating activities coming from product supply agreement. It has been 10 years after inception and after investing billions of dollars in science and product development. Thank you to all our employees, scientists, of course to our investors and to all of you that have believed in Moderna.

Let me turn to slide 5 for my closing remarks. As a snapshot of Moderna in October 2020, we have accomplished a lot and continue to have a broad pipeline that continues to progress well. We have fully enrolled Phase 3 program with mRNA-1273. We now have four Phase 2 trials with CMV, (inaudible) vaccine, VEGF with AstraZeneca, and now OX40 ligand. Seven ongoing Phase 1 programs, and 12 positive Phase 1 studies. Our vaccine franchise has six programs in development, addressing major unmet needs. We have five immuno-oncology programs in the clinic, four programs in rare disease, and two programs in autoimmune disease. Our foundations have never been stronger with

32,000 participants and patients in our trials. We have now over 1200 employees. We have an international manufacturing capacity and capabilities with our partner, Lonza, ROVI, and Catalent. And we have strategic partnerships with companies like Merck, AstraZeneca, and Vertex.

At the end of September, we have a strong balance sheet of $4 billion. I'm very proud of what we have accomplished so far and where we stand as a company. The next few weeks [ph]at most are going to be quite historic for Moderna. I will now turn it over to Tal to talk about clinical updates. Tal.

Tal Zaks {BIO 19987702 <GO>}

Thank you, Stephane, and good morning everybody. Let me give you a quick overview of our pipeline progress and starting with our COVID vaccine. The Phase 2 study looking at safety and immunogenicity in 600 participants is ongoing. Dosing has been completed, but we remain blinded while the final immunological testing is being conducted. Once we have the results, we will share them. As a reminder, the safety data from this trial have of course been shared with regulators prior to the start of our Phase 3 COVE Study. That is now fully enrolled and I will share some details shortly. For our CMV vaccine mRNA-1647, we shared positive Phase 2 data at our annual R&D Day in September and the data enabled us to select the 100 microgram dose to take forward in our pivotal Phase 3 trial, which is expected to begin in 2021. For Zika vaccine, we showed the positive Phase 1 results and are preparing for Phase 2.

On the pediatric front, I'm happy to announce that our hMPV/PIV3 Phase 1b age de-escalation study has resumed dosing toddlers aged 12 to 36 months, following a pause that was related to COVID-19 disruptions.This is the first mRNA vaccine to be given to toddlers. In addition, the first cohorts of adults participants in the Phase 1 study of our RSV vaccine mRNA-1345 has now been fully enrolled. As a reminder, this is also in age de-escalation study similar to the hMPV/PIV3 study and the plan is ultimately to also dose toddlers.

In another core modality, the Systemic Secreted & Cell Surface Therapeutics, we shared the positive Phase 1 data from additional cohorts of the chickungunya antibody program during our annual R&D Day in September. Importantly, we demonstrated not only potentially therapeutic levels of the secreted systemic protein, but that a two-dose road -- regimen with a week between doses was safe and well tolerated and led to the predicted increase and chikungunya antibody productions. This demonstrates our platform's ability for repeat dosing. I'd further note that as a result of rapid systemic clearance, no significant accumulation of our lipid nanoparticle was seen after administration of the second weekly dose.

Moving to slide 8 and the updates from our pipeline of candidates across the four exploratory modalities, and starting with our personalized cancer vaccine the PCV, the randomized head-to-head trial of PCV with KEYTRUDA versus KEYTRUDA alone in the adjuvant melanoma setting is ongoing. [ph]A reminder that our Phase 1 study continues with patients in the various tumor types, who were treated in the monotherapy core -- cohort A and combination cohort B are in follow-up and the Phase 1 expansion cohorts of

cohort C is enrolling patients. Cohort [ph]D in the adjuvant melanoma is also ongoing. For the infant tumor immuno-oncology, I'm happy to report that we have dosed several patients in the ovarian Phase 2 expansion study. Recall that we initiated this part of the study just last month, and I believe the teams focused on moving this trial forward along with the support of our clinical investigators has been very productive. Our triplet program in this modality also continues to enroll and dose patients in Phase 1. In our systemic intracellular therapeutics modality, study -- startup activities have resumed for the PA program following disruptions due to COVID-19. In addition, Nature published a preclinical study on this program. For the MMA program, recall that we announced at R&D Day that we would take forward a next generation development candidate mRNA-3705, which recently received a rare pediatric disease designations from FDA. And finally regarding our partner led programs, the Phase 1 KRAS with Merck and the Phase 1 interleukin-12 and Phase 2a VEGF studies with AstraZeneca are all ongoing.

Slide 9 is a snapshot of our development pipeline and please note that eight preclinical programs across three different modalities that we didn't touch upon during the clinical review, bringing the total number of programs in development currently to 21.

So let me move into more detail to mRNA-1273, our vaccine against COVID-19. Slide 10 is a broad overview of where we are. mRNA-1273 elicits a robust immune response across species and can protect [ph]human and nonhuman primates from the virus taking hold in both the nose and the lungs. In the clinic at the 100-microgram dose, we observed consistently high levels of neutralizing antibody titers across all adult age groups and these titles were higher than those seen on average in convalescent sera. And the Phase 3 COVE trial has completed enrollments meeting our expectations and I'll give you more details on the demographics in a moment.

Let me briefly review the Phase 1 results that were published in The New England Journal of Medicine. mRNA-1273 has been generally safe and well tolerated as the Phase 1 safety data at 100 microgram across the adult age cohorts demonstrate. As it relates to tolerability, the most common solicited adverse events were headache, fatigue, myalgia, chills, and injection site pain, the majority of which were mild to moderate in severity and self-limited. Of note, local and systemic reactogenicity were more common and more frequently moderate in severity after the second dose. One severe solicited systemic adverse event occurred after the second dose and that was fatigue in the above age 71 age cohort, who received the 100-microgram dose. What is important is that these flu-like symptoms are expected, their transient and generally mild to moderate in nature, and I believe they correlate with the underlying potency to stimulate an immune response and high levels of neutralizing antibodies. Importantly, there were no vaccine-related serious adverse events in this trial and no patterns of concern for any clinical labs. And while these numbers are still small, we did not see a difference in safety or reactogenicity profile between younger and older adults. As it relates to the immunogenicity, I would make three points regarding the data. First, we see the same level of neutralizing antibodies in younger and older adults. Second, we see these levels consistently in everybody who received the vaccine. And finally, these levels are higher than those seen on average in the blood of people who had been ill with COVID-19 and whom we expect by and large to be immune to a second infection. Now if you follow the timeline, you see that the high levels of antibodies are achieved quickly upon boost, and I believe the speed and quality

of this immune response speaks to the T-cell supports and puts us in a good place to have durable protection.

Slide 13 shows an overview of our Phase 3 COVE Study, which is now fully enrolled with 30,000 participants. The full protocol can be found on our website. Noteworthy points from this slide include the one-to-one randomization between 100 microgram of mRNA in the vaccine arm and placebo. Every participant in this study was expected to be at higher risk than average of infection. That was inclusion criteria number one. And a significant proportion of subjects were stratified as being risk -- at risk of worse outcomes from COVID-19 should they get infected. These are people over 65 years old or those under 65 years old, but with chronic conditions that are risk factors for disease.

So how did we do in terms of demographics. We are very proud of the hard work of our clinical team, our collaborators at NIAID, and our clinical trial sites that led to the successful recruitment of a diversion representative study population, which is similar to the census of our country, with 37% of study participants coming from diverse community. And you can see the breakdown on the left side of this slide. We enrolled 6000 Hispanic or Latinx participants and 3000 black or African American participants. Age distribution is shown in the middle, and of note about 2/3 of the trial participants are older than 45, as the gender distribution was close to evenly [ph]split as is seen on the right.

So what about risk factors for severe COVID-19 disease. The greatest risk factor is age and a quarter of participants were over the age of 65. In addition, 17% were younger but still at risk of severe disease by virtue of comorbid co-conditions, such that 42% of trial participants are in the high-risk strata of having the worst outcomes should they get infected. There is another way of looking at it, which looks at the breakdown of the chronic conditions that put people at risk, shown on the right. These include diabetes at 36%, severe obesity at 25%, significant cardiac disease at 19%, and 18% with chronic lung disease. I would note that all -- that all in all, over 8000 of the participants in our study are living with these chronic conditions. And if you do the math, you'll realize that a significant proportion of participants in the COVE Study had independent risk factors of both an older age and comorbid conditions.

So slide 16 sums it up. Our Phase 3 COVE Study is representative of the many diverse populations that make up our nation and by extension, many parts of the world and many people could identify with our study and can find themselves in it.

As we're anticipating the results of our COVID-19 vaccine study, let me take a few minutes to review the statistical analysis plan on what happens next. As many of you know, we have two interim analyses at 53 and 106 events and a final analysis triggered at [ph]151 events. At the first interim analysis based on the statistical plan in order to call it a success, we will need to show vaccine efficacy of 74% or greater. From the graph on the left, you can see that there is a 50% probability of meeting that hurdle, assuming a vaccine efficacy rate of 75%. So there is an element of chance here as well. At the second interim analysis, vaccine efficacy of 57% or greater is required to meet the statistical hurdle. And the probability of meeting this is actually 95% if the actual true vaccine efficacy is 75%.

For the final analysis as per FDA guidelines, at least a 50% efficacy is required. And again, the probability of meeting that primary endpoint in the final analysis is in the high 90s, assuming that our true vaccine efficacy rate is 75% or higher. But we also need to remember is what's not on this graph. All of these assumptions are driven by the imperative to ensure that we have a high degree of confidence. And I'm talking about statistical confidence that once one of these boundary conditions are crossed, not only do we have an initial point estimate about the vaccine efficacy but we have a 95% confidence interval that the true efficacy, not the point estimate of the sample exclude 30% or is higher than 30%. And I'm sure we'll be coming back to this crucial point in the future.

So in each interim analysis, there are three potential outcomes. Either the study meets the statistical hurdle which is 74% at the first interim and greater than 57% at the second, enable us to trigger the full analysis required to evaluate whether to proceed with regulatory submission and of course the trial remains blinded and data continue to accrue at this time. The study may not meet the statistical hurdle and then would continue to the next milestone. Or the study is determined to be futile.

As we have committed to and have been transparent throughout the Phase 3 clinical program, today we released the informed consent form of our Phase 3 study on our website. And we will continue to be transparent, will announce the results and next step once the first interim analysis has occurred.

(technical difficulty) also driven by the fact that from a distribution standpoint, we're ready. We expect the mRNA-1273 be distributed within existing infrastructure. There is nothing [ph]new required that hasn't already been used for years with many other vaccines.

Specifically the advantages of mRNA-1273 that allows us to do this includes the ability to package and ship boxes in any configuration, housing small or large quantities of vaccines, storage conditions of minus 20 degree Celsius for six months, refrigeration temperatures of 2 to 8 for up to a week, and room temperature conditions for up to 12 hours after thaw. No special handling or dilution is required prior to vaccination with mRNA-1273. And by the end of this year, we expect to have approximately 20 million doses ready to ship in the US.

With that, let me turn it over to David to take you through the financials.

David Meline {BIO 6397419 <GO>}

Okay. Thank you Tal.

Turning to slide 21 in the deck, we ended Q3 2020 with cash and investments of $3.97 billion compared to $3.07 billion at the end of Q2. The increase is primarily driven by $1.1 billion of customer deposits received in the third quarter for a potential supply of mRNA-1273. Net cash provided by operating activities was $763 million for the nine months ended September 2020, compared to net cash used of $360 million for the same period in 2019. The reversal from cash used to cash provided by operating activities is driven by

total customer deposits for the nine months ended September 30th of $1.2 billion received for a potential supply from mRNA-1273.

Cash used for purchases of property and equipment was $44 million for the nine months ended September 2020 compared to $25 million in 2019.

Total revenue was $158 million for Q3, 2020 compared to $17 million for the same period in 2019. Total revenue was $233 million for the nine months ended September 2020, compared to $46 million for the same period in 2019. Total revenue increased for both the three and nine-month periods in 2020, primarily due to increases in grant revenue from BARDA to accelerate development of mRNA-1273.

Research and development expenses were $344 million for Q3, 2020, compared to $120 million for the same period in 2019. Research and development expenses were $612 million for the nine months ended September 2020, compared to $370 million -- $378 million for the same period in 2019.

The increases for both three and nine-month periods in 2020 were mainly due to increased mRNA-1273, clinical development activities and headcount and pre-launch inventory build up. Overall in both periods, we saw a significant increase in expenses for the prophylactic vaccines modality as a result of our focus on mRNA-1273.

General and administrative expenses were $49 million for Q3, 2020, compared to $28 million for the same period in 2019. Expenses were $109 million for the nine months ended September 2020, compared to $84 million for the same period in 2019. The increases for both periods were mainly driven by increases in personnel, outside services, and setup costs associated with preparation for commercialization of mRNA-1273 globally.

Turning to selected cash flow information on slide 22. On the top half of the page, we present information from our 10-K and 10-Q filings and on the bottom part, we provide the quarterly trend and also items to take into consideration when assessing the evolution of this trend in particular for Q2 and Q3 of this year. Cash provided by operating activities and for purchase of property and equipment was $719 million for the nine-month period ended September 30th, and $874 million in the third quarter alone.

Excluding deposits received for potential supply of mRNA-1273 and the Vertex upfront payment, cash used in operating activities and for purchase of property and equipment was $296 million in the third quarter. This compares to $118 million in the second quarter of this year, excluding customer deposits received in Q2. The increased cash used of around $200 million in Q3 compared to previous quarters is consistent with our expectation, as we are making substantial investments in manufacturing and potential global commercialization activities for mRNA-1273 COVID vaccine candidate.

Let me now give you an overview about where we stand with regard to commercialization activities. Please turn to slide 23. On slide 23, you see listed supply agreements that we have announced publicly today. As a reminder, these include the agreement with the US government for a 100 million doses and options for an additional 400 million doses. We

just announced the deal with Japan for 50 million doses. Canada has confirmed 20 million doses with an option for an additional 36 million. We have also signed agreements with Switzerland, Israel, and Qatar and there are several other countries that have signed agreements that have not been publicly disclosed.

We are thankful for the trust the governments around the world have placed in us to deliver a vaccine for their countries. All of these agreements contain provisions for deposits and have contributed to our 3Q, 20 deferred revenue value of $1.2 billion, including $600 million from the US government. We continue to work with the European Union, where we are in advance discussions to supply 80 to 160 million doses.

Negotiations with other countries are also ongoing including with COVAX on the tiered pricing proposal. As a reminder, pricing for agreements with smaller volume were executed at $32 per dose or $64 for a two-vaccination course, for $37 per dose or $74 per course. We remain on track to fulfill these contracts with anticipated supply between 500 million and 1 billion doses in 2021.

Turning now to our 2020 financial update on slide 24. On an overall basis, we now expect net cash provided by operating activities and purchases of property and equipment in 2020 in the range of positive $0.1 to $0.3 billion. The change compared to our update in Q2 is primarily driven by the increase in customer deposits for the potential supply of our mRNA-1273 as well as upfront payments for recently announced collaboration agreements with Vertex and Chiesi.

Let me provide you more color on the individual components of our financial outlook. With regard to the ongoing investment in our portfolio, excluding our COVID vaccine candidate and associated activities, we remain on track to our prior outlook. We expect net cash used in operating activities and purchases of property and equipment to be approximately $0.4 billion in 2020, reflecting an improvement of $0.1 billion from prior outlook. This change is entirely driven by business development activities and related upfront payments as investment levels remain consistent with prior outlooks.

Turning now to the financial impacts of our rapidly advancing mRNA-1273 COVID vaccine. First, expenses that fall under the scope of our BARDA agreement, these are primarily research and development activities to drive the COVID vaccine to licensure and scale-up activities on the technical development and manufacturing side as we expect a relatively close matching of expenses and reimbursement. We do not expect these activities to materially impact our cash flow and hence these are not shown separately on slide 24.

Next, looking at the COVID vaccine related net investments primarily for manufacturing a product to be commercialized in the US and internationally. We expect the cash impact of COVID related investments to be $0.5 billion to $0.65 billion in 2020. This includes approximately $0.2 billion in capital investments with the balance of the expenses related to raw materials and production activity in our network. Additionally, this investment includes initial commercial infrastructure build out and costs related to our supply agreements.

The sum total of net cash used in operating activities for all of Moderna's business is currently expected to total $0.9 billion to $1.05 billion before consideration of customer deposits. Including the customer deposits received by the end of September which sum to $1.2 billion, we expect the total net contribution from cash provided by operating activities and used for purchase of property and equipment of positive $0.1 billion to $0.3 billion. We expect this number to increase as we continue to receive further deposits.

Turning now to slide 25. As we progress towards approval and commercialization of mRNA-1273, there is heightened interest in several areas of accounting that will increasingly impact our reported results as we move forward. Slide 25 highlights some key areas, which will change with an approval event, for example, an Emergency Use Authorization in the United States. Costs associated with pre-launch inventory are currently fully expensed to R&D expense in the period incurred. This includes cost for acquired raw materials as well as production costs. After an approval event, we will capitalize our inventory to the extent that the commercialization is determined to be probable, and we expect future economic benefits from sales to be realizable.

In the third quarter of 2020, we expensed pre-launch inventory of $52 million, largely raw materials. The costs associated with purchases of property and equipment or leased assets related to our mRNA-1273 program are evaluated for all (technical difficulty) assets with alternative use will be capitalized. Examples of these assets include IT and general production infrastructure. Assets acquired to meet the current production needs of mRNA-1273 and before product approval will be expensed immediately as costs are incurred. This reflects the fact that Moderna does not yet have other platform products approved or commercialized.

After a regulatory approval event, when PP&E and leased assets are no longer required to be assessed for alternative use, such assets will be capitalized. In Q3, we recorded $10 million of PP&E as expense. On product sales, customer deposits for potential supply of mRNA-1273 are recorded as deferred revenue and will be recognized as revenue when control of approved product has been transferred to the customer and customer acceptance has occurred.

In Q3, we recorded $1.1 billion of incremental deferred revenues associated with potential future supply of mRNA-1273. No product revenue was recognized in the quarter. Accounting for the BARDA grant follows a reimbursement model where we will recognize revenue as we perform services and closely match expenses as they are incurred. As of 31 December 2019, we had $982 million of federal and state accumulated net operating loss carry forwards and $471 million of net deferred tax assets, which were fully reserved as we concluded that realization of our net deferred tax assets was not yet, more likely than not to be realized. After a regulatory approval event and as we expect to utilize the NOLs, we will reverse and release the valuation allowance or portion of the allowance, which will result in a tax benefit in our income statement.

This concludes the financial update and I turn now the call back to Stephane.

Stephane Bancel {BIO 15174250 <GO>}

Thank you, Tal and David. In closing, I would like to step back for a few minutes. Across the world. We are all, rightly so, very focused on the pandemic, the race against the virus both with therapeutics and vaccines. The Moderna team has been incredibly focused in 2020 on getting mRNA-1273 to the market in record time. But an important part of my role is to look into the future. Not only at the next few weeks, but the next few years. And to look at the big picture, not only to look at Moderna.

I believe Moderna entered 2020 in a strong position -- with a strong cash position of approximately $1.3 billion with a diverse clinical portfolio of vaccines and therapeutics across six different modalities. We have always focused on a portfolio approach to reduce technology risk. We have 20 development candidates. We have sustained over nine years since inception, large investments in platform science, mRNA and LNP formulation.

We have established a very broad and strong IP portfolio with sustained large investment in process development. We own the fully integrated plant that allowed us to grow from raw materials to fill vials for all of our clinical needs at scale and with unprecedented speed.

As I look at the end of 2021, 14 months from now, I believe that if we launch mRNA-1273, we will exit the COVID pandemic crisis in a unique position. We should have a strong cash balance at the end of 2021. It will be made of $4 billion at hand as of September 30th, 2020. Plus the cash flow that we should generate in fiscal year 2021.

The US government has taken a very thoughtful approach with Operation WARP Speed or OWS. They decided to support three vaccine technologies, including mRNA to diversify risk to ensure we got several vaccines to a finish line for the US citizens. They decided to back only two companies for technology. Moderna was one of the two companies that the US government ordered 100 million doses from. That is a very important market access. We are grateful for the trust of US government placed in us, our (inaudible) process and our technology and we are very thankful for their help.

Moderna retains worldwide rights to develop and commercialize mRNA-1273. Without a corporate partner, Moderna will realize all the profits from a COVID-19 vaccine. We intend to reinvest the returns from the sales of a vaccine into our pipeline development and hope to bring more medicines to the market. I believe that the long-term strategic implication are large. We should have a unique cash position at the end of 2021. Moderna has been built to scale because mRNA is a new formation molecule. We invested [ph]relentlessly in science upscale that no other company could thought, in robotics, in digital, in process development, in a large manufacturing plant. We have always been limited in the last five years with cash. I believe that this is about to change in a very material way during fiscal year 2021.

The approval of mRNA-1273 for commercialization would provide a unique derisking of the entire Moderna vaccine platform. We use the same chemistry to make each mRNA vaccine. We use the same manufacturing process to make the mRNA. We use the same chemistry for lipids, the same manufacturing process to formulate the mRNA in our lipid. Think about what this team could do over the next five to ten years starting from a

growing cash balance of $4 billion and the knowledge that our technology leads to approved vaccines. I believe 2021 will be the most important [ph]infection year in Moderna's history. Early on, we recognize that mRNA could be an entire new class of medicines. We always said since day one that it made no sense that this could be a one-product company. It will be zero if we fail to make safe and efficacious product or it would be a new class of medicine changing medicine forever. Our mission to deliver on the promise of mRNA science to create a new generation of transformative medicines for patients is one we strive for every single day. In 2020, we didn't do it alone. We had many partners, the NIH, BARDA, Lonza, ROVI, Catalent, PPD, the clinicians that executed our clinical trials, and our team. I'm very thankful for the clinical trial participants for their trust and their participation in our trials. With that we'll now be happy to take your questions. Thank you. Operator.

Questions And Answers

Operator

Thank you.

(Operator instructions)

And our first question comes from the line of Salveen Richter with Goldman Sachs. Your line is now open.

Q - Salveen Richter {BIO 15151450 <GO>}

(technical difficulty) COVID19 vaccine. So just given the commentary from the recent FDA AdCom on COVID19 just would like your thoughts here about how you intend to unblind potentially on the first interim or post the full [ph]free looks in the study. And then secondly just timelines around a vaccine EUA just given some of the commentary and I think Dr. Fauci talking about at January green light for vaccines. Thank you.

A - Tal Zaks {BIO 19987702 <GO>}

Yeah, hi, this is Tal. Let me try and take that. I think the bottom line here is that we feel I think an obligation to the participants of the COVE Study, especially those for whom an EUA will be appropriate that there is a way for them to ultimately benefit from what they themselves have contributed to. And of course I think we all listened intensely to [ph]Vertex last week. There is a balance to be had here. The way I think this is going to happen at the end of the day, unfortunately the cases are accruing. We're in a period of increasing transmission and so I expect that there will be some time between knowing that the bar has been crossed for efficacy, doing the analysis and discussing with FDA and part of that conversation is finding the right balance of how long do you continue to collect blinded data and what is the type of data that one can collect post blinding but still on trial. I mean, if you do the math if you're looking for very rare safety events, for example, then an unblinded study actually could give you power to detect that even more than a blinded trial. So a lot of these elements, I think, are going to go into the conversation that we're having with FDA. And I'm confident that together with them, we will find the right balance as to how to operationalize this. As it relates to the timing, I

think we're on track to have the first interim in November. I think, I expect unfortunately that we're going to be on track for additional cases occurring in December and beyond. And so the totality of data in the coming months I think will cross that threshold I anticipate for efficacy and the rest will be a dialog with FDA and other regulatory agencies on the right process by which to ensure we demonstrate the safety and efficacy and ultimately make the vaccine available.

Q - Salveen Richter {BIO 15151450 <GO>}

Thanks, Tal.

Operator

Thank you. And our next question comes from the line of Matthew Harrison with Morgan Stanley. Your line is now open.

Q - Matthew Harrison {BIO 17603148 <GO>}

(technical difficulty) all the information this morning. I guess two related questions from me. Tal, can you comment at all about the attack rate that you're seeing in the study. I think given the Pfizer comments earlier this week, there is a lot of confusion among investors about whether the attack rate in these studies mirrors what we're seeing in the general population or if it's somehow lower than what we're seeing in the general population. And then a related question, something else that I think has come up a lot is this concern about functional unblinding potentially due to people recognizing some of the features of the boost and that may be leading towards certain people taking on different behavior, which may lead to this lower event rate. So I was wondering if you could talk about -- if you have a concern about functional unblinding and especially related to the fact that you obviously have the placebo data from the Phase 2 studies, do you have a much better idea of placebo adjusted tolerability versus what we've seen from an open label study. Thanks.

A - Tal Zaks {BIO 19987702 <GO>}

Hey, Matthew. Let me try and give you a sense of how I see the data. First of all, my sense from the emerging data is that the attack rates of our trial participants do mirror what we see in those zip codes where the subjects are coming from. It's not a surprise, because if you look at the demographics of what we've been able to achieve in the COVE Study having so many people of minorities older with comorbid conditions. So it's on par with expectations, I think [ph]writ large. And unfortunately with the current attack rates not slowing down, the math that we're doing, it's this paradox of more attack rates out there worse off for our subjects unfortunately, but the data, we'll get there. So that's my sense.

Now, there is a balance to be had which I think is -- I've tried to address in the first question that not just us but everybody in the field is struggling with, which is the accumulation of data versus the eventual unblinding of participants and how does that all play into regulatory expectations. And I think we'll continue to have this dialog in the coming weeks.

You're -- the concern you raised about functional unblinding, yes I show that. I think we all due to a certain degree. We chose a dose that we believe is optimal in the sense that people may get some transient flu like symptoms, but it's worth it for the opportunity to prevent this disease. I don't think this leads to lower event rates per se. I think my biggest concern is that if anything, it would bias us against vaccine efficacy, right. If people behave because they think they got something and that modifies their behavior then and if anything, you would expect that the behaviors would be such that the placebo recipients would be less at risk of getting infected and the vaccine recipients would be more at risk of getting infected. So at least from a statistical and robustness of the data, it shouldn't have any adverse effect. If anything, it should hurt us. But I don't expect this ultimately to be significantly changing the event rates. And if I look at the macro pictures, (inaudible) said, I think we're going to be on track unfortunately for where we anticipate being. Over.

Q - Matthew Harrison {BIO 17603148 <GO>}

Thanks very much.

Operator

Thank you. And our next question comes from the line of Ted Tenthoff with Piper Sandler. Your line is now open.

Q - Edward Tenthoff {BIO 1880164 <GO>}

Great, thank you very much and thank you for all of your hard work in bringing 1273 forward, amazing to see the company turning cash flow positive, a huge milestone. I wanted to get a sense for cost of vaccine at the price or at the quantities that you're talking about for next year with Lonza. Thank you.

A - Stephane Bancel {BIO 15174250 <GO>}

Ted, it's Stephane. As we've said in the past, no we are not disclosing cost of goods for obvious competitive reasons, so I won't be able to answer that question.

Q - Edward Tenthoff {BIO 1880164 <GO>}

Very well. Looking forward to data coming up. Thanks.

A - Stephane Bancel {BIO 15174250 <GO>}

Thanks, Ted.

Operator

Thank you. And our next question comes from the line of Michael Yee. Your line is now open.

Q - Michael Yee {BIO 15077976 <GO>}

(technical difficulty) what do you think is going on with the event rates. I know that you said you actually believe you on time. So, maybe it's a question more in part based on the competitor and related to that. Do you actually know your actual event rates and therefore you do you feel every day that you're seeing the numbers and feel very confident about November and your competitor missed that timeline, so I think everybody's nervous about that. So maybe just make a comment about what do you think is going on in general.

And then secondly because you've been on is actually a pretty high interim and I think you've actually commented on that, maybe just make a comment about if we don't hit that, what that will mean for folks and I think it has to do mostly with the [ph]office spend. So that's why I'm not too concerned, but maybe just make a comment about that as well.

A - Tal Zaks {BIO 19987702 <GO>}

Thank you. Yeah, this is Tal. Look, I can't comment about our competitors. I don't know their data so I leave that to them. I can repeat what I said about our sense. We do of course see the data coming in. There is a small team at Moderna that's aware of the cases that's following up. That number is of course being kept confidential to minimize speculation here. But I can tell you that overall it -- since we are following the zip codes and the counties from which these participants come, we have pretty sophisticated models of what to expect and I think we're on track for those expectations. So I think we should be on track for that first interim sometime in November as we have articulated.

You raised a valid point about the interim and thank you for asking that. Hitting that interim is going to be a function of what the actual vaccine efficacy is and an element of luck on the distribution of the first batch of data you see. Not hitting it doesn't mean the vaccine doesn't work and in fact doesn't even mean that the vaccine has a less than 75% efficacy. We could easily not hit it and yet come back on the second interim and demonstrate an 80% or 85% efficacy. That's kind of the chance of how the stats work.

I think the alpha spend, et cetera, you're correct. This is a conservative design and maybe it's an opportunity to dispel a notion. The fact that we crossed the boundary at interim doesn't mean it's less powerful than a final from a pure statistical standpoint. Once you cross that boundary, you have the same statistical conviction that you would have had on the final. Now, I think the way I think about the data here is irrespective of the point at which we cross the boundary, the trial will continue blinded for a period of time, data will continue to accrue and as long as the trial continues blinded, we will get better and better with more and more data to increase the level of certainty we have on all the endpoints of the trial.

So in that regale -- in that regard for me the first crossing of the interim is just the basis that allows us to go and have confidence to start doing analyses and proceed down the path of regulatory interactions so that we ensure that ultimately access is not delayed to people when there is such a high need out there in our communities. Over.

Q - Michael Yee {BIO 15077976 <GO>}

Thank you.

Operator

Thank you. And our next question comes from the line of Gena Wang with Barclays. Your line is now open.

Q - Gena Wang {BIO 18848097 <GO>}

(technical difficulty) do you also see safety in a blinded format. If so, how's that compared to the Phase 1 profile. And then two questions regarding the interim analysis. So if first interim -- if you miss the first interim, is this due 4 to 8 weeks to hit the second interim. And then for the first interim, what is the futility bundling?

A - Tal Zaks {BIO 19987702 <GO>}

Let me take that. The safety, yes we see the totality in a blinded fashion. I would remind you that the Independent Data Safety Monitoring Board that's been appointed by the NIH and sees not just our trial, but also the other US OWS sponsored trials. In parallel, sees both the blinded and the unblinded data. Writ large, I can tell you that so far we're not seeing anything unexpected. So the trial continues and in that regard, I don't expect surprises when we eventually unblind.

Your second question around the timing is I think it's a matter of weeks between the first and the second interim (technical difficulty) months. Now, I can't be more precise because obviously it's a function of the future transmission rates in areas and I hope that they go down. But for now this (technical difficulty) weeks, not longer.

In terms of futility, I think the boundary is to show that this is going the wrong way. It's specified to the degree that we felt it was appropriate to specify in the protocol. Beyond that I can't say that it's the reason you have a Data Safety Monitoring Board, you've got on that panel several statisticians and several experienced clinicians. So it is where I expect them to exercise their judgment and experience and they're looking at it closely. Over.

Q - Gena Wang {BIO 18848097 <GO>}

Okay, thank you.

Operator

Thank you. And our next question comes from the line of Cory Kasimov from JP Morgan. Your line is now open.

Q - Cory Kasimov {BIO 3009346 <GO>}

Thanks guys for taking my question. This is Matthew on for Cory. Just on the COVE trial and in light of subject mix and commentary that rates are tracking geographically with infections. I'm wondering what your assumptions are for the proportion of patients with SARS-CoV-2 infection that you expect to ultimately go on to become symptomatic.

A - Tal Zaks {BIO 19987702 <GO>}

So let me make -- let me answer that in maybe a simplistic form. The tracking is first and foremost of symptomatic cases because we're not routinely swabbing people just to check PCR's people self-identify. The asymptomatic infection rate will be determined based on serology that distinguishes between infection and immuno -- immunization by later comparing antibodies against nucleocapsid versus spike protein. So, we are primarily aware of the symptomatic infections to begin with and that is the parameter that we're primarily tracking as it relates to the epidemiology. Hope that answers the question.

Q - Cory Kasimov {BIO 3009346 <GO>}

Yeah, I guess maybe just a follow-up. So when you say that rates are tracking the zip codes, what is the data that you are gathering from outside the trial to benchmark it to zip codes.

A - Tal Zaks {BIO 19987702 <GO>}

(technical difficulty) reporting of case rates and infection rates together. It's -- we've got a couple of independent expert panels and teams here that compile the totality of the data that emerges from the various surveillance programs and sophisticated models to create those predictions.

Q - Cory Kasimov {BIO 3009346 <GO>}

Great, thank you.

A - Tal Zaks {BIO 19987702 <GO>}

I -- if you're asking me to describe what's under that hood, it's a complicated black box for me. But I can tell you that the number that it spits out ultimately looks very close to the number that we see on a daily and weekly basis at this stage. And that's what gives me the confidence.

Q - Cory Kasimov {BIO 3009346 <GO>}

Got it, thanks.

Operator

Thank you. And our next question comes from the line of Geoff Meacham with Bank of America. Your line is now open.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey guys, this is Alec on for Geoff. Thanks for taking our question. Can you talk a bit more about the tiered pricing proposal with COVAX. What would this look like? And if you can talk about the agreement specifically, what's the logic of a tiered structure versus just a set price for a certain amount of doses seen in the other supply agreements. And on the Japan supply agreement, and I suppose on most of the OUS supply agreements, how do

you plan to allocate manufacturing between your plants and Lonza's and are there any logistical constraints that would limit the vaccine produced in Norwood geographically.

And I guess just lastly what's being done to ensure consistency of vaccine produced between both your own internal and the external manufacturing sites? Thanks.

A - Stephane Bancel {BIO 15174250 <GO>}

Hey, Alex, Stephane. So it's a lot of questions. If I forget something, let me know. So on COVAX, what we want to do is to make sure that the vaccine is available around the world. As you know, we believe based on the quick -- I mean on the early development data that the vaccine has a chance to be protective across different age range and we think it's very important, and so we want to vaccine to be available to help as many people as we can.

The tier pricing is very typical of what Gavi has done in the past. As I'm sure you are aware, COVAX is being run by Gavi and CEPI. And so the idea here is to propose to low-income countries and middle-income countries a price that is lower than the price being paid by developed countries or high-income countries. And so that's basically the idea. And so of course, we're not in the position to disclose those prices today because the discussions are ongoing with COVAX. But we'd want to make sure as a company that we are able to provide vaccines at a lower cost for low-income and middle-income country. In term of quality across the board, I would say it's very typical of what is done in any biopharmaceutical companies when you have several sites, in term of a quality organization, technology transfer, validation, and so on, to ensure that the product that is made at Lonza -- in Visp at Lonza, in New Hampshire at Moderna (inaudible) is of the same quality and the same spec.

And then in term of allocation, so as we said in the past, we set up the supply chain -- with the US supply chain, Moderna, Massachusetts and Lonza, New Hampshire to focus initially on the US. We set up the supply chain in Lonza, Visp to be initially focused outside the US. As -- and I think this is going to really hold (inaudible) I would say two quarters after launch. After such a time, we are going to set up the supply chain in term of regulatory filing so that products can be moved around. So if we get to a point where we have kind of [ph]sold out the products in the US, that makes sense to be sold in the US, we will be able to ship products from the US to international and vice versa. We want to set the supply chain so that if at some stage we need more product in the US, we can import from Switzerland more products into US. So we're trying to set up a supply chain that allows us to be very flexible and nimble to react to the needs of the marketplace. I hope that answers the question, Alex.

Q - Geoff Meacham {BIO 21252662 <GO>}

Yes. Very helpful, thanks.

A - Stephane Bancel {BIO 15174250 <GO>}

Thank you.

Operator

Thank you. And our next question comes from the line of Hartaj Singh with Oppenheimer. Your line is now open.

Q - Hartaj Singh {BIO 18796450 <GO>}

Great, thank you. Thanks for all of the data presented. Just a couple of quick questions, one is a non-COVID related on CMV 1647. You've got a worldwide -- (inaudible) worldwide rights to. How are you thinking in terms of as you grow the organization, Stephane, on a worldwide basis with 1273. Can you just talk a little bit on how that'll help you with 1647 when the time comes to launch that and even prepare for worldwide trial with 1647. And then secondly, is it just wrong for us to assume that part of your initial revenues from 1273 to COVID-19 vaccine could be sort of one-offs, depending on how governments order them versus kind of a more like-for-like basis comparison on a year-for-year basis. Any way to think about that going forward? Thanks for the questions.

A - Stephane Bancel {BIO 15174250 <GO>}

Thank you, Hartaj. So on the, I would say, non-COVID organization, Stephen Hoge has spent a lot of time since the beginning of the pandemic to refocus on that one (inaudible) we've done to allow us as a company to both deliver 1273 at the kind of historic record time and not slow down the rest of our pipeline, which of course is very important for Moderna and Moderna's future and for patients. (inaudible) Tal has really focused most of his time on 1273 and taking this product from literally computer, into Phase 1, into Phase 2, and into completing successfully the COVE Study and all the interaction with regulatory agencies around the world on the one hand. And then Stephen has really focused on the non-COVID portfolio and so what we have done is we've been hiring quite a lot. If you look at the headcount numbers, we've been hiring quite a lot and we're going to continue to do so into the next quarters so that we can have the right scale in term of development, so that we don't slow down the development pipeline of a great asset like CMV or PCV or other asset because we don't have the right teams on the ground.

And as we get closer to commercialization, we will of course hire people dedicated to that. We've already actually hired the Head of Marketing for CMV because it is very important. We believe given there is no product on the market for CMV, in terms of disease awareness, a lot of women do not know about CMV and what CMV could do to their pregnancy. And so we think there is a great opportunity while the Phase 3 is running to re-drive up CMV awareness and I think you know in the post-COVID world where people are going to be, I believe, much more attuned to infectious disease. And given the similarity of outcome between Zika and CMV and given what happened in Latin America a few years ago, everybody is highly aware of Zika. And so I think there's a great opportunity for us to actually prepare the market to increase the speed of the uptake of CMV by preparing the market a few years before launch, which is what we are doing.

In term of the revenues, as we described I think in the Q2 call, we really believe there is a pandemic phase of the COVID vaccine and then an endemic phase, [ph]which will be set up mostly on boosting. As has been discussed a lot in the medical community, we do not know across the different vaccines how long we're going to be working for and so we

believe most probably -- especially the elderly or people at high risk, we're going to want to boost their immune profile. We do not know yet if it's going to be once a year, once every two years, once every three years most probably will depend on the [ph]population. We have no way to know that, but to run the clinical experiments, which we are all doing across the industry.(inaudible) different vaccines will have different duration of protection and so, indeed I think you're thinking about in the right way, which I think there's going to be for quite a while pandemic contracts that are going to be set up like some that we have set up to catch -- actually start vaccinating people. And then there's going to be follow-up contract that [ph]I can anticipate for the boost. So that's kind of how we think about it. Does that make sense, Hartaj?

Q - Hartaj Singh {BIO 18796450 <GO>}

Yeah, now that helps a lot, Stephane. Thank you.

Operator

Thank you. And our next question comes from the line of George Farmer with BMO Capital Markets. Your line is now open.

Q - George Farmer {BIO 4629715 <GO>}

Hi, good morning. Thanks for taking my questions. I was wondering if you could comment on what happens if you don't hit the primary endpoint of this study -- of the COVE Study? And you do head meaningfully on second any -- secondary endpoints, which could be quite important. I mean certainly reducing severity of disease could be something regarded as meaningful. Have you thought about that? And my second question is if you do get an EUA, do you -- does it -- does the existing supply agreement have -- having -- come into play, do you start drawing down on your in -- inventory commitments following EUA or do you wait until you get full approval. Thanks very much.

A - Tal Zaks {BIO 19987702 <GO>}

So, George, this is Tal. It's an interesting point you raised. Typically, if you don't hit the primary, you don't get to take credit from secondaries the way the stats are laid out. I think in this case, if there is biological possibility, then of course we go and discuss with the agency what the data are looking like (technical difficulty) because I anticipate we will actually have the opportunity to cross it early, we may have those discussions ahead of time while more data is accumulating and if we fail to hit it but the trial continues blinded given I think the exigent circumstances, we can go and have a dialog with the agency on what we've seen so far. But I'd say the proximal answer would still be the conservative one which is if you don't hit the primary, it's very hard to take credit for secondaries. It's going to be up to the regulators. I think the answer to your second question is an easier one. Yes, the supply agreement kicks in and US government, I would expect would start to take the supplies once we have an Emergency Use Authorization. Over.

Q - George Farmer {BIO 4629715 <GO>}

Great, thanks very much.

Operator

Thank you. And our next question comes from the line of Alan Carr with Needham & Company. Your line is now open.

Q - Alan Carr {BIO 15355437 <GO>}

All right, thanks for taking my questions. Stepping away from COVID ones. You all mentioned a month or last month that you'd like to revive that flu program. I am wondering if you could give us some more details around that. Is this something that is going to be (inaudible) as a seasonal flu vaccine or something that you see as a universal vaccine. And if you can give us any updates on timelines around that.

A - Stephen Hoge {BIO 17925815 <GO>}

(multiple speakers) So what we announced last month is that we're looking at strategically and we're going to begin building a business in seasonal influenza. I'll remind you that we do have already clinical data in pandemic influenza from two different programs. And so we've shown the ability to generate a productive immune response to influenza virus as well. We haven't provided clarity yet on when we expect that program to move into the clinic. We will in the future provide those updates as we get closer to that time, but we have suggested both it's an interesting market to try and do better on because there is a substantial still unmet need in influenza and we do think our platform can be differentiated for a couple of reasons. One obviously that we can bring many antigens to bear. And the second, the opportunity to do combinations -- potentially combinations even with other viruses that might need seasonal boosting. And so we'll provide an update as soon as we declare the development candidates we normally do and move forward towards clinical development, but we're quite excited by that opportunity at this time.

Q - Alan Carr {BIO 15355437 <GO>}

Great, thanks for taking the questions.

Operator

Thank you. And our next question comes from the line of Umer Raffat with Evercore. Your line is now open.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi guys, thanks so much for taking my questions. I had a couple, if I may. First, maybe starting from an easier one. What's the cycle threshold you're using for the PCR positivity. Is it about 34. Second, if you could confirm if there have been any one-off cases of COVID infection for participants who got 1273 in Phase 2 or Phase 2.

And then finally, I know the slides mentioned rapid protection in lung and nose of non-human primates. But in The New England Journal data, we did see at least one primate at the 100 dose with detectable [ph]line on the nasal swab. So I guess what I'm getting at is as a base case, despite the requirement of symptoms, is it reasonable to assume that we

could actually see one off cases of nasal swab test positive for COVID? Thank you very much.

A - Tal Zaks {BIO 19987702 <GO>}

Hi Umer. Let me take those questions. Our cycle threshold, I don't think the number is meaningful because it's not the same number on different assays. It's part of the assay characteristics so I can't really comment because I don't believe you can compare those numbers across different assays.

On the participants in the Phase 2, I think we've had a case or two but since we're still blinded, I can't really comment on what that means. The question on nasal swabs, yes. Well, first of all on the primate, you're right, there was one primate with transient and relatively low levels in the nose and the rest were [ph]stereo.

I think that when we talk about sterilizing immunity, I think that concept is confused by the high sensitivity that we have. So what we mean by that, well, if I am immune and I've got IgGs (inaudible) I've got IgAs, as our data show we have and I'm walking down the street and somebody sneezes on me a whole bunch of SARS-CoV-2 and I'm and 49th street. Well, if somebody stops me On the 50th street and sticks a swab up my nose, they're probably going to see some detectable virus from that cloud I just inhaled a block ago. It doesn't mean that the antibodies aren't kicking in and the virus isn't getting cleared. It's a question of timing and sensitivity. So it depends then on how you measure and when you measure and what are the triggers for measuring.

In our trial, we test people who raise their hand to say they've got a symptom and a reason to be tested. The only asymptomatic testing that occurs is really at day one and day 29 to make sure that we're excluding the right people and not confounding adverse events with actual disease. But short of that, we're not just randomly doing swab test. So I hope that, that answers your question as it relates to detection. Over.

Q - Umer Raffat {BIO 16743519 <GO>}

Thank you very much.

Operator

Thank you. And our next question comes from the line of Mani Foroohar with SVB Leerink. Your line is now open.

Q - Mani Foroohar {BIO 20015167 <GO>}

Hey guys, thanks for taking my questions. I know there's a lot of focus on the COVID-19 (inaudible). Specifically, I wanted to dive in on [ph]massive financials a little bit. So did I hear right that for the quarter about $10 million of P -- of what would otherwise be PP&E were expensed. And so when moving that back to CapEx, give us the base from what to go here. And secondarily on that, how should I think about the tempo of CapEx growing over the next 12 to 24 months presuming a successful EUA and global commercialization. And then I have a follow-up question after this.

A - David Meline {BIO 6397419 <GO>}

Yeah, so in terms of the capital deployment if you look at the quarter three, we had $10 million which I mentioned that was 1273 related, that was expensed. What also we invested was $12 million in the quarter, which was capitalized. So $22 million in total. And I think that's a reasonable run rate. You will see some increase here as we finish the year and we trend up on investing in preparation for launch and the full capacity that we're putting in place.

As that continues into next year, I think it's fair to understand that the capital deployment is going to increase somewhat, including the possibility in the fourth quarter of additional expensed capital to the extent it's deployed prior to the approval, which we do expect more to happen.

And then if I may, also keep in mind the inventory expensing, which is not strictly capital investment but the acquisition of raw materials and the cost of production. And of course we're ramping that production in anticipation of an approval. And therefore, it's quite likely that we'll have a fairly significant amount of expensed inventory occurring in Q4, prior to approval.

And as you would understand the impact of that is that as we start commercializing product post approval, the cost of that product will be essentially zero from a cost of goods perspective until we've sold through that inventory that we produce prior to approval.

Q - Mani Foroohar {BIO 20015167 <GO>}

Okay. That's really helpful. And then hopping over on to the non-COVID pipeline. I may have missed if it was mentioned, what's the timeline to get the next [ph]log of datas from the Oxford ligand program and when should we think about having a reasonable number of patients with that asset on top of a PD1 -- on top of an approved PD1 therapeutic?

A - Tal Zaks {BIO 19987702 <GO>}

Let me try and take that. This is, Tal. So it's oncology and data, I think, is determined by not just patient accrual, but the events that happen on trial. And so it's really hard for me to predict, which is why we've been very clear on how many patients we have and where are we. But I think the next tranche of data, I would anticipate will be once we have a sufficient number of these patients with ovarian cancer on trial. And that is already in combination with PDL1 blocker, so that should be informative for response rates once we have sufficient patients with sufficient follow-up. Over.

Q - Mani Foroohar {BIO 20015167 <GO>}

Great, that's helpful. And as a final question, I'll bob back to financials. Obviously your stock has been quite volatile over the course of this year, as have many of your peers.Given that and given that you continue to build out your infrastructure and headcount anticipation of expanding the pipeline and launching commercially presume -- presuming an EUA for COVID-19, how should I think about modeling or how should we think about modeling stock-based compensations relative to the overall R&D expense,

SG&A expense. So will the portion go up as you start to have more of a sales force or will it go down as you get scale. Just how should we think about that, either in absolute terms as a proportion of total -- as a proportion of spend, just how should we think about modeling it next, say 12 months?

A - David Meline {BIO 6397419 <GO>}

That's a very good question and I guess I'd have to get back to you. I guess, I'd start with the point of view that the trend would be stable, but we'll have to get back to you on that.

Q - Mani Foroohar {BIO 20015167 <GO>}

All right. Thanks for taking my questions and congratulations on (technical difficulty).

Operator

Our last question comes from the line of Navin Jacob with UBS. Your line is now open.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi, this is a Alana on for Navin. Thank you for taking our question. So from what you've seen in your nonhuman primate studies, what impact on prevention of infection through the viral colonization and viral transmission do you expect to see from 1273? And then secondly sort of a broader question is do you think that your vaccine or any vaccine in general will be able to deliver sterilizing immunity?

A - Tal Zaks {BIO 19987702 <GO>}

Yeah. So that's a good question. Let me tell you how I think about it. Again, as I alluded before, I think the concept of sterilizing immunity is a function of how you actually test for it. We'll be able to demonstrate prevention of infection, at least as measured by serology, which is to say maybe somebody saw a little bit of the virus but actually the antibodies kicked in and they never established enough to demonstrate antibodies against the other parts of the virus, the nucleocapsid. That's actually what we will be measuring in the Phase 3 as a way to show protection from asymptomatic infection.

I'm hopeful that we will be able to demonstrate that. I anticipate that, I mean just on first principles, what is the hardest thing for a vaccine to do, it's to sterilize. What's the next hardest, it's to prevent asymptomatic. What's the easiest, it's probably to prevent the most severe disease. And so that's how I think about the order of expectations. But I think what you're really getting at is what is going to be the ability of this vaccine to prevent transmission and I think because I don't anticipate any easy direct measure of this, we're going to have to do some math once we see the data.

I expect that if people get less sick and certainly less severe sick, they will be spreading less because I think there is while we have asymptomatic spread, we also have symptomatic spread. And so -- and in fact I think the higher the symptoms at least early in the disease, potentially the more viral shedding you see. So that's a complicated equation that I think in a nutshell is going to be very hard to answer directly through some concrete

measurement in the trial. What we will hope to show is that we prevent asymptomatic infection based on serology. We will clearly hope to show prevention of symptomatic infection, that's the primary endpoint. And based on first principles which were -- by the way, Phil Krause from FDA alluded to and agreed with last Thursday, one would anticipate that if you prevent symptomatic disease you should -- it should be even clearer that you're preventing the more severe manifestations. Over.

Operator

Thank you. And that concludes today's question-and-answer session. I would now like to turn the call back to Stephane for any closing remarks.

A - Stephane Bancel {BIO 15174250 <GO>}

Right. Thank you, operator. Thank you everybody for your time and your question and your support. (inaudible) stay safe everybody. Bye.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.
