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MRNA.OQ - Moderna Inc at JPMorgan Healthcare Conference (Virtual)

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PRESENTATION

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

All right, good morning and once again, welcome to the 40th Annual, and unfortunately second time virtual, JPMorgan Health Care Conference. My name is Cory Kasimov, I'm the senior large cap biotech analyst, and it's my pleasure to introduce Moderna and CEO, Stéphane Bancel, who really needs no introduction.

Please note that following this presentation, we will move right into a Q&A session where you can send in questions via the little blue Ask a Question button on your conference portal. And if it's easier, you can also e-mail me questions as well, and we'll do our best to work them into the conversation.

So with that, Stéphane, thank you for being here. Let me turn it over to you.

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

Well, thank you, Cory. Good morning, good afternoon or good evening, everyone, and happy new year to everybody. Wishing you a healthy and happy year.

So let me start by reminding everybody we'll be making forward-looking statements. You can look at the disclaimer on our website, our disposition is already there.

And also that in some countries, the COVID-19 vaccine has been approved. But in some countries, like the U.S., it's authorized. And there are some important safety information that I wanted to remind you of. Again, you can find this on our website.

So let me start maybe very briefly by talking about 2021 before talking about the future. We were very humbled to have a privilege in 2021 to help so many people in the world, literally hundreds of million of people, which is quite extraordinary for a young biotech company. We announced that we shipped 807 million doses of our vaccines around the world. We are very pleased that around 25% of those doses were shipped to low-income and middle-income countries, to have an impact, to really help as many people as we can around the globe. And we're reporting this morning that the product sales should be around \$17.5 billion. They are, at this stage, unaudited. We'll get the final numbers in a few weeks.

As you can imagine, there has been a very significant and very rapid scale-up of our company. And I'd just like to share with you a couple key metrics that are really important to me as I looked at where the company was in early '21, and where the company is now as we exited '21 and are entering '22.

As you know, at the beginning of '21, the only data that we had about our vaccine were the phase III data showing very strong efficacy of around 95%, holding very nicely at around 6 months at 93%. What is very exciting to us as we get more and more data, and there's some very recent data, again, from Singapore, highlighting this that were just presented. There is a lot of real-world evidence from the U.S., from many countries in Europe, the Middle East and Asia, showing a very strong and enduring efficacy of mRNA-1273.

The other piece, too, as you know, earlier in the year of '21, we were very supply-constrained. And as you know, one of the reason we believe we have very strong real-world evidence of efficacy with our vaccine is we have a higher dose than other mRNA vaccine. And so that was a big drain into the manufacturing supply, when you need 3.3x more mass of product to provide very strong protection to people.

But as we pivot into '22, we shipped 300 million doses in Q4, giving us a run rate of 1.2 billion doses, what we've already demonstrated. And because of the additional capacity that we announced last year, that will be online in Q1 this year, we are still on track to be able to provide 2 billion to 3 billion doses of boosters if that was required.

The other piece, too, in early '21, we had no commercial infrastructure. And now in the most important 10 countries around the world, we have teams on the ground helping us already increase the market share of our product.

We have a very dynamic environment. And on November 4, for Q3 earning call, we announced we had EUR 17 billion of signed APAs. I remind you that at Moderna, when we have a signed APA, there's a contractual commitment and an upfront cash payment made to reserve the capacity, so \$17 billion, and up to \$3 billion of options.

We've announced this morning that we are increasing those expectations, that as of today, we have \$18.5 billion of signed APAs and we have now around \$3.5 billion of options. It's important to know that there's a lot of discussions ongoing as we speak, that those numbers are mostly heavily toward the first half of the year. And the discussions that are ongoing with many countries right now are really above -- about the fall of '22 and how do countries get themselves ready to protect their population in the fall of '22 leading into the winter of '22, '23.

What's important to keep in mind is that the COVID-19 vaccine, or Spikevax, is our first product. As you know, mRNA is an information molecule. We have built, over the last 10 years, a platform. I won't go through the entire slide in detail, but we have a lot of late-stage programs now. The CMV program is in Phase III. We have the RSV program in Phase II/III. The flu is in Phase II; like several COVID boosters; the Zika vaccine; the personalized cancer vaccine; and the VEGF-A program that had the positive Phase IIa data that AZ presented at the American Heart Association, which is going to move to late-stage studies.

And the company now has a very broad pipeline of actually 40 development programs. We are very excited about our respiratory vaccine franchise, I'll come back to it in a minute. The latent vaccine franchise is also building up nicely with CMV in Phase II, but now EBV for Epstein-Barr virus, the virus causing mononucleosis and a long -- of long-term issues in health is now in Phase I in human. HIV should be in the clinic pretty soon. We have a few more of other vaccine. We want to keep helping the world for outbreaks and pandemic readiness, like Zika or Nipah.

And on the right, you see that on the therapeutic side, this is going to be a very exciting year in 2022. We should get data in immuno-oncology. We should get clinical data also in rare genetic disease and in autoimmune disease.

The company has grown a lot. We have now close to 3,000 employees at the company. And we're very, very humbled and privileged that the culture of the company stays very exciting. And for the seventh year in a row, our employees have voted us 1 of the top 10 company to work for in the biopharmaceutical industry ranked by the magazine, Science. We have now commercial presence in 12 countries around the world. And what's very exciting to me looking forward is the cash balance that the company has today. We have \$17 billion of cash in the balance sheet. And when you look at this platform that we have built, we have always been cash-constrained in the past, and the ability that we have to invest is something that is really exciting.

If you look at where we are going, as we described before, we have 4 franchise that we are focusing on, and they are ranked by other priorities for us as a company.

The #1 is a pan-respiratory annual booster vaccine. So what we want to do is to provide the world a single annual booster dose that protects people across a wide range of respiratory viruses.

When you think about SARS-CoV-2, as we have shared now, you can see this slide is an old one from our Vaccine Day of last year, this is what we shared at the time. That we believe that, of course, first, this virus is not going away. It's going to become endemic like many viruses that we have long to live with as humans. And as you're going to see, the morbidity waves are going to be less and less, but the groups at high risk, 50-plus, health care workers, immunocompromised people and many more populations, are going to need very regular protection to ensure that they do not get severe disease and get hospitalized.

And the vision that we have for this pan-respiratory annual single-dose booster is basically a franchise that's going to evolve every year. And there are 3 big axes that we care about.

One is time. Over time, what we're going to do as a company is to provide protection against more and more viruses. So we started with COVID-19, of course, but we are working towards adding flu to COVID in the same dose, then adding RSV to COVID and flu, then adding more and more viruses. And we really want to build the world portfolio in that single shot. So we protect people from disease, hospitalization and death.

The other piece that we're going to be doing over time is to update, to the circulating strain, the vaccine. We're doing it as we speak, as you know, for the fall of 2022. We are working on an Omicron-specific booster. And we believe the next product's iteration as a booster will need to contain Omicron. We will also be able to adapt by geography, and I will come back to that in a minute, by different countries, and of course, also by age group. Because as it has been reported for epidemiology study, sometimes, they're very young need different protection compared to the older population against respiratory viruses.

One other thing that we are doing in addition to our product strategy is to build in-country mRNA vaccine manufacturing capabilities. We've already announced a partnership with 2 governments, in Canada and in Australia, where we are building factory in the country to be able to adapt the product to the country in partnering with the government. Those are 10 years agreement of supply.

Our second priority is around latent viruses. CMV, EBV and HIV are the first ones, but there are many more that we're working on in the labs.

The third priority is to use mRNA where we include a protein to allow us to do product like oncology product, cardio product, rare genetic disease and autoimmune disease.

And the fourth one is gene-editing enzymes, where we want to use mRNA to code gene-editing enzymes because we believe that there are very interesting new enzymes that are able to use our mRNA platform to go after during gene editing.

As we build the company, we want to make sure we build the company in the right way. And so while you also have a product strategy, we're also investing to make sure the company is built in the right way and is strong and scalable. We're investing in Africa, where we believe the world needs a factory in Africa, up to \$500 for up to 500 million doses. We are also working already towards our pledge to achieve net zero carbon by 2030. We're investing in a big new center in Cambridge, Massachusetts towards our Science Center. We have launched an AI Academy recently, and we also announced a Moderna Foundation to help have a big impact on the world.

In term of capital allocation, our #1 priority, of course, for the \$17 billion of cash we have is to reinvest in the business. As you can see, we have increased over the years our R&D investment tremendously. Pre-pandemic, we invested around \$500 million per year in R&D. This year, in 2022, we expect to invest 5 to 6x more, \$2.5 billion to \$3 billion in R&D. In CapEx, we used to invest less than \$100 million. In this year through reinvestments in the U.S., but also in Europe, in Canada and Australia, to go up to \$800 million.

Our priority #2 for capital allocation is external investment to broaden and strengthen the platform of Moderna. We've announced in the fall a gene editing partnership with Metagenomi where we get access to their next-generation enzymes through gene editing, where we use the mRNA cassette and our lipid to get into cells. That technology already available, that we want to just expand.

This morning, we announced yet another partnership that we are very excited about with Carisma. That's an oncology company that had developed very interesting technology to go after CAR-M. And what we want to do, unlike CAR-T, that we are mostly focused on liquid tumors and ex vivo, is here, to be able to do an in vivo treatment where people get an IV injection. We don't have to take their blood, send it to a factory and do a very complex, lengthy and expensive manufacturing process. All done in people's body. And that's a technology, CAR-M, that is able to not only target liquid tumor, but also solid tumor.

We've also announced our third priority, is to keep returning capital to shareholders. And we announced shareholder buyback plan last August.

So if you think about the company moving forward, I am really excited about the strategy that we have. I think we have a unique chance through this mRNA platform to impact humans in a very large scale. We want to provide a single-dose annual booster so that humans don't get sick, hospitalized or die of respiratory viruses. We think this is within reach, and we won't stop until this goal is achieved.

We believe humans suffer long-term disease and have a big impact on the quality of their life because, in young age, they're infected by latent viruses. There's no vaccine against CMV, against EBV and many other latent viruses, and we won't stop until those vaccines get to market and are available to young people to protect them so they have a high-quality life as they get older.

We're very excited to use mRNA technology to go after the big killers in cancer, autoimmune disease, rare genetic disease and also of course cardiology. And we're already planning for the next generation of technology where we can, we think, leapfrog current gene-editing technology. We're doing gene editing 2.0 using our mRNA platform.

The team at Moderna is very committed to really work hard and collaboratively with our partners to impact as many lives in the world as we can. What excites us is this is just the beginning. Because mRNA is information, we believe many more drugs are going to come to help protect a lot of human around the planet.

So with this, I'm going to stop my remarks, and I'll be happy to have questions from you, Cory.

QUESTIONS AND ANSWERS

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Terrific. Thank you, Stéphane. It's amazing what's been accomplished in 10 years. Definitely goes quick. I guess -- and first of all, let me remind everybody, you can ask questions as well, and I'll work them into the conversation with the little portal toggle. We have a couple in there already, but let me start.

I just want to ask, what do you think are the key lessons from Omicron and how much things have changed in the last, I guess, 6 weeks now? And kind of what do you take from this going forward?

Stephane Bancel - Moderna, Inc. - CEO & Director

So the most important piece is that the vaccines, I mean our vaccine, works very well. If you look at the data that's coming out from the real-world evidence, is that despite with the virus that has mutated quite a lot, that has been massively reported, people that have got a 3-dose regimen of Moderna's vaccine, holding very nicely against hospitalization and death, which is what, of course, we all care about.

So the virus, as we all know, is very contagious. The number of cases is exploding, literally, around the world. But I think that people that are boosted are well protected. If you know anybody who has not been boosted or even, God forbid, not been vaccinated, please make sure they get vaccinated as soon as possible, or boosted.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Okay. You just -- when you think about sort of, I guess, chasing new variants like Omicron with varying specific vaccines versus creating perhaps a multivalent approach. Do you worry to be too late by the time an Omicron-specific vaccine was widely available?

Stephane Bancel - Moderna, Inc. - CEO & Director

Well, I think what's going to -- with a multivalent, as you describe, is to build a portfolio of tools that help us react to whatever the biology and the virus is giving us in term of variants. We think given Omicron is really becoming dominant everywhere, that providing an Omicron in the potential fall '22 vaccine, an Omicron component, we think is going to be important. Our scientists are working very closely with top scientists in the world and public health leaders across the world to figure out what other mRNA component might be important in the vaccine to provide a very strong spectrum of protection.

So because we care about short term, with neutralizing antibodies. We also know the very important potential of T cells. It has a lot of published data, have shown that we have a very strong repertoire of T cells that are there, which we believe are very important in preventing severe disease.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Okay. Now Moderna previously suggested we may finally enter an endemic phase with COVID later this year. Is that still your expectation? Or has it shifted?

Stephane Bancel - Moderna, Inc. - CEO & Director

So it's our expectation -- again, I want to be humble because virology is always tricky. And I think people around the world were very surprised by the number of mutations just in 1 jump in Omicron. But if you look at the data, I mean, because there are so many cases happening, a lot of people unfortunately are going to be infected by Omicron, are already infected. When you look at the cases reported, they do not include at-home testing. They did not include people that are asymptomatic but positive. And every time somebody is going to be infected with Omicron, they're going to mount an immune response to it. So it's going to educate the immune system on new epitopes, it's going to boost the neutralizing antibodies.

So the piece that is impossible to predict at this stage is do we have a new variant after Omicron that becomes more severe? I think the piece that we've been "lucky" as a world with Omicron is that it seems to be less virulent, especially for people that are vaccinated. But we're always a day away or week away or month away from a new variant that has some mutation that makes it more virulent, which is why we are working as hard as we can to get this new booster out containing Omicron so that we are able to go into very large quantities.

As you know, we're at a run rate already of 1.2 billion doses if you look at what we've done in Q4, but that was mostly primary series. As a planet moving to a boosting mode because most people on the planet in the next few months will have access to a vaccine for primary series, including in the South, we continue to believe we could get 2 billion to 3 billion doses of boosters available this year.

If you look at other manufacturers and that capacity, I think we should really be in a world where we can very quickly, if it needs be, scaling a new variant-specific booster to protect for the fall next year. So I'm confident we'll be able to get the job done.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Okay. And what do you think an endemic phase is going to look like? And how drastic of a difference do you think it's going to be compared to what we've all been experiencing over the last year, 1.5 years, 2 years?

Stephane Bancel - Moderna, Inc. - CEO & Director

So I think that as people get vaccinated and boosted and infected, you're going to see like, with other viruses, a broad portfolio of T cell repertoire that people will have and neutralizing antibodies and so on. And I think what's happening, with other respiratory virus like the flu or other coronavirus like OC43, which is circulating in the community and causing around 10% of hospitalization pre -- the end of 2019, pre-COVID. And so if you look at those, what you see, basically, it really depends on the population.

People that are 50 and above, people that have a high risk because they have an autoimmune disease, they have cancer, they're immunocompromised; they are health care workers, they are closed and get infected a lot. Those people, we anticipate, we believe will need an annual booster. Will every 25-year-old who are healthy want or need an annual booster? I think it's too early to tell. They might need another booster every 2 years or 3 years, we'll have to see with the data.

But we believe that we have a very big role to play. If you look at the epidemiology data of OC43, people that are above 50 get reinfected every year. And this is really the population we want to focus very strongly with this combination vaccine that I spoke about, where we want to have COVID-19 boosters and flu boosters in the same dose, and RSV and OC43 and more and more viruses per year to provide a very, very broad protection to people against respiratory virus.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

All right. And then, Stephane, based on your recent data, how are you thinking about the need for a 50- or 100-microgram booster dose for different segments of the population?

Stephane Bancel - Moderna, Inc. - CEO & Director

Yes. So we're still learning through the real-world evidence. Unlike other products, we don't have in the years and years of clinical studies to learn about the product as we are chasing the virus during the pandemic. What is clear, which is not surprising, is that 100 micrograms give you higher neutralizing antibody than 50. That is not surprising.

And I think as we're seeing used, and recommended by the FDA and the CDC, people that are high-risk, like immunocompromised, it makes sense that they get the 100-microgram. For somebody who is healthy, who has already been primed, getting the 50-micrograms as the data shows is highly protective.

So I think like in other fields of medicine, there might be an evolution that people at high risk maybe get a higher dose, people that have lower risk but do not want to be hospitalized want to kind of reboot the immune system, get the 50-microgram and will really prevent hospitalization and deaths.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

How are you thinking about the evolving kind of pricing landscape of COVID vaccines? And the trend over time, particularly as -- it's potentially more vaccines as well as therapeutics become available this year and beyond and as we enter an endemic phase?

Stephane Bancel - Moderna, Inc. - CEO & Director

Sure. So we have priced the vaccine at the pandemic level. As you know, the price of vaccine compared to other type of vaccines is pretty low. We thought it was the right thing to do across the world so that funding was not an issue. As you know, we've also proposed an at-cost price for low-income countries. But if you look at the value being provided by the vaccine, it is quite remarkable to see the cost savings to the health care system to somebody vaccinated. We believe that in the high-income countries, the vaccine is currently underpriced.

We believe the world is also starting to see a lot of difference between the vaccine. As you know, in 2020, when everybody was in clinical studies, people assumed the vaccines were going to be very similar. What we have seen now through clinical studies is not the vaccine -- they are not all similar. There's been also some reason why, if you look at the high-income country, it has really become an mRNA market. In the U.S., in Europe, even in the U.K., the boosters is either Moderna or Pfizer Booster.

And so I think that governments, health care professionals and also the consumers are seeing the difference in vaccines. There's just been recent reports from Singapore where they have shown again that Moderna seemed to be showing the strongest protection against deaths across 4 or 5 vaccines that they looked at.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

All right. I want to definitely work in some non-COVID-related questions, but I do have a number of investor questions here that I'll get to first. First one is very long, so I'll just ask the first part of it.

It says, thank you for all the positives that Moderna brings to public health via its vaccines. Is there any further understanding on long COVID and how it is characterized and/or prevented? Is it reasonable to start thinking about long COVID as perhaps a chronic disease, once one has it, one never gets rid of it? And how does that change the value proposition for COVID vaccines?

Stephane Bancel - Moderna, Inc. - CEO & Director

Yes. So we are still learning a lot about lung COVID. There are quite a number of scientific hypothesis of what causes it. I think it is too early from what we have seen to come to a conclusion. But I think this goes back very much, to me, to the need for vaccination and the need for boosters.

As we know, the vaccines prevent hospitalization and death, but also they prevent infection and as well as adapting the vaccine to the circulating strain is very important. If you look at the data that we saw against Alpha and Delta, our vaccine had a very high efficacy against infection. With Omicron, we saw a drop of efficacy against infection because of a big genetic drift. But if you look at the real-world evidence, in the first 30-ish days that the data is available, for example coming out of the U.K., you see a very strong protection of infection.

And so I think the best thing we can do as a community and as individuals to reduce the risk that any of us gets long COVID is to get vaccinated and to get boosted regularly.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Okay. Next question is, I understand you're in the final stages of selecting the country to serve as the site of your new African facility. When do you expect to break ground and then eventually begin production? In the meantime, how are you scaling up manufacturing capacity for the Global South?

Stephane Bancel - Moderna, Inc. - CEO & Director

Sure. So let me start by the global piece. As I shared quickly in my remarks, we should have this year 2 billion to 3 billion doses of boosters available for the planet. That is a lot when you look at the population of the planet and you looked at basically the Chinese have -- are using Chinese vaccine for the Chinese market, so that's already taking a lot of people out of the equation.

In terms of the Africa plant, we are in the final process. We have a couple of countries down, I'm talking 2 to 3 countries left, on the list of diligence we have done. I expect that it's a matter of a month or so maybe to be able to finalize the country and to announce it.

The design of the plant has already been worked on by our team. And so as soon as the country is selected, we just need to finalize the site with that country. But we've not lost time. In parallel, we have developed the drawing of the sites and our engineering teams are already working hard to be able to break ground as soon as possible.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Okay. Another one that's in here was something we discussed already, but says I don't believe that BioNTech has said they will have an Omicron-specific booster, still under consideration. Have you already definitively decided this?

Stephane Bancel - Moderna, Inc. - CEO & Director

We have not definitely decided this. It is just the current thinking. Again, we are very data-driven as a company. There's going to be a lot of real-world evidence that is coming in the coming weeks from the U.S. but also from U.K. and Europe. We have all the options on the table. We could, of course, keep making the current vaccine and make it available at a much larger manufacturing scale. We could have Omicron-specific vaccine. We also would have a multivalent combining several components. We've tried in the clinic the Alpha variant. We tried the Delta variant, we tried the Beta variant. And so we have all those components ready.

So we just need a few more weeks to get the real-world evidence data to get the data where we can test human serums of all those vaccine constructs against Omicron. And with that data set, talking to public health leaders, health ministers and so on in key countries, we'll be able to decide what do we think is the best product to protect as many people as we can for the fall of 2022.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Okay. Last one I see here on COVID, and then we have a couple that are outside of COVID. What is the latest on the COVID vaccine patent dispute with the NIH?

Stephane Bancel - Moderna, Inc. - CEO & Director

So we're having discussions with the NIH. As you know, there was just disagreement of inventorship, and we are working towards resolving this. Moderna scientists have been working on the mRNA construct, the mRNA technology, which is part of the pattern, is the technology that Moderna has been working on for 10 years. And so I'm quite optimistic that we should be able to find a path forward.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Okay. A couple more that go outside of COVID, and then I'll work some of the mine in as we wrap up here. Do you see a potential future application for mRNA-encoded therapeutic antibodies against intracellular targets.

Stephane Bancel - Moderna, Inc. - CEO & Director

Yes, that's highly possible. We've actually already done that in the labs in preclinical models where you basically make an antibody, which we have shown in the clinic, we have the chikungunya antibody. So you basically design it. We got a signal peptide that allows the protein -- or the antibody, sorry, once made in the cell, to be released in the serum. And so we have worked on that, and that's something that for some application could be quite interesting.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

All right. And then the last one in the queue right now is how do you think about endless RNA? How about the technology and application of eRNA in the future? Is there any plan for Moderna to work on this?

Stephane Bancel - Moderna, Inc. - CEO & Director

So we are very focused on RNA and we are always looking at new technologies, and we have been for a while. At this stage, we don't have anything to share publicly. But given we are so long in mRNA, as you can understand, any time there's a new RNA technology, our scientists are going pretty deep at it.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

All right. So wanted to ask you about flu, following your recent Phase I/II flu readout. So what are your expectations for the Phase II interim data that are anticipated earlier this year? What do you think would support quickly advancing candidates like 1011 and 1012?

Stephane Bancel - Moderna, Inc. - CEO & Director

Sure. So first, let me start by a bit summarizing the Phase I data, which we're very happy about. So in the Phase I data, we achieved exactly what we wanted to achieve, which was showing non-inferiority to the best products available today. Our goal had never been to have the best flu vaccine out of the gate. Our goal was to move very quickly to get to market of COVID and flu in a single dose. That is our objective because as we talk to governments -- and as you can imagine, through this pandemic, we've talked quite a lot to government and are doing this on a daily basis.

The notion to have a vaccine as good as the current -- as the best vaccine on the market for flu and COVID in a single dose is something that governments are very, very interested by because they worry about compliance. They worry about the chance to have people at risk getting 2 shot, 1 for COVID booster, 1 for flu boost in the same fall/winter season. That's a big worry to government. And so they say, "Look, if you can give us very quickly a flu vaccine as good as what's on the market -- as well as one of the best on the market, not the average or the weakest one, the best ones, and COVID, we're game."

And so our strategy is to be a bit like in the tech world, which is we want to start with a product that as good as the best product on the market and then increase the efficacy, which is what we are doing by adding more HA, as Dr. Hoge, our Head of R&D, described at -- when we closed the data; but also adding new antigen like the DNAs that are not available today in the commercial vaccines against flu. And that's our strategy.

So what you're going to see is a very quick iteration, which is possible with this technology, which is not fully possible with other technologies where your manufacturing process is a liability to you because it is adapted to the same product.

And so we are very excited. In the Phase II, if we have confirmation of the strong level of neutralizing antibody and we have a confirmation of a tolerability profile, will be go -- flying into a Phase III. And at same time we'll go also in the clinic with a combination of flu plus COVID because we'll have a dose confirmed by them to bring the COVID plus flu to the market as soon as we can.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Okay. How do you think about reactogenicity or just about safety tolerability with a flu-COVID vaccine or even a pan-respiratory vaccine in the future?

Stephane Bancel - Moderna, Inc. - CEO & Director

So the piece that is important to understand is that what is causing the tolerability? Is it the lipid or is it the antigen? What we believe, with our technology, because we have a biodegradable lipid, which is not the case of other mRNA player, we believe that what is causing the reactogenicity profile is the antigen. Because with our technology, you make so many copies of the antigen that you code in the mRNA, that when you go back into human injecting the product, again, you have a higher reactogenicity.

You see it very well. If you want to look at the Phase III data of the COVID-19 vaccine, we had more reactogenicity at the booster than you had at the prime at the same dose. And they were mostly systemic, not local. In systemic side effects, like chills, fever, headaches and things like that are really a reaction of your immune system.

Another data point that makes us confident that we can get to level with several components in a single dose is our cancer vaccines. Our cancer vaccine use exactly the same lipid, the manufacturing process and the same chemistry for the mRNA. So you can read across a lot. We have dosed the mRNA vaccine against cancer, the PCV program, at 1 milligram per human. That is 10x the dose of a high dose of COVID-19 vaccine. It's 20x the dose of the current booster authorized, 20x the dose. And we dose those patients every 3 weeks for 10 weeks in a row, and there is no issue.

So we really believe that the reactogenicity that we saw with COVID and that you see in the flu program is linked to a reaction of your immune system because the product is so performant that you have a lot of copy of the protein and that immune system is not happy about it. And as a consequence, make a lot of antibody against the protein, which is what you want to get long-term protection against infection, hospitalization and death.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

So now that messenger RNA has so quickly become a recognizable and highly valued technology, how does Moderna continue to stay ahead of emerging competition?

Stephane Bancel - Moderna, Inc. - CEO & Director

So science investments. One of the thing we are very blessed by is the \$17 billion of cash that we have today. 2,700 employees. We only do mRNA. We don't do small molecule. We don't do large molecule or cell therapy. We only do mRNA. We have dreams and like nightmares about mRNA. And you have a very dedicated team working on that field.

And as I said in some of my remarks, I mean, look at where the company was in 2019, \$500 million in R&D, we are very capital-constrained. In this year, we're going to invest \$2.5 billion to \$3 billion in R&D just in mRNA.

And so investment in science, I was recently with our process engineers, spending a full afternoon doing technical reviews. And the things they are investing around mRNA is mind-blowing. It's 400 very talented, very dedicated engineers. This is bigger than the entire R&D part of some other companies that are getting into the field.

And then IP. During the pandemic, we said we didn't want to enforce our IP because mission #1 was to deal with the virus and the pandemic. But as we go into the endemic market, we have a lot of patents. We have been doing this for 10 years. We have very, very broad patent that applies on a lot of things, and we want to make sure that our IP is respected and enforced.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

All right. And I guess piggybacking on all this is, with the success of mRNA-1273, you've alluded to the \$17 billion in cash you now have. How does this play into your evolving thoughts around capital allocation?

Stephane Bancel - Moderna, Inc. - CEO & Director

So I think it's similar to what we said when we started activating that strategy. As you know before, Cory, you've known us for many years, we were cash flow negative. So capital allocation was very simple, it was invest in the business. But where we are now, we stay extremely excited about the future of the company.

We believe this is just the beginning. It's a bit like if you go back to the first recombinant product, when Genentech and Lilly launched growth hormone and insulin. They didn't stop investing in R&D, they invested. And then a whole field emerged with very wonderful drugs that have helped the lives of hundreds of millions, maybe billions of people by now.

And so we see exactly the same thing. We don't think it's the end of the beginning, we think it's the beginning. And so our appetite to invest in mRNA is literally endless.

And then as you saw, we have 2 partnerships we already announced, and there's many more that are cooking as we speak, is we want to expand the platform. We really do not care where the technology comes from. We want the best technology to plug in on the mRNA platform, when we can leverage our mRNA expertise, our lipid expertise. You saw it in Metagenomi and you saw it this morning with yet another partnership, that we enable that technology to do things that could not be done using other technologies.

And so those are already our 2 first priorities. And then at the right time, we will return capital to shareholders through share buyback as appropriate. But again, this is the third priority. Priority #1 is to expand the company. We have a platform.

And traditional biopharma is not platform-based. As you know, because you followed the industry for a very long time, a lot of companies get 1 drug to market, everybody is scratching their head, okay, what's the next drugs? We have 40 products, you can go and look at the data, the [transferability] of technology across products and across therapeutic area is really incredible. We are moving into the age of digital medicines. And I think people do not understand yet the velocity and the breadth of what's going to happen in the next 3 to 5 years.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Okay. Well, with that, we are out of time. Stéphane, thank you once again for making the time for us today. I always enjoy the conversations with you. So thank you very much.

Stéphane Bancel - Moderna, Inc. - CEO & Director

Thank you for the invitation, Cory. Stay well.

Cory William Kasimov - JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst

Great. You too.

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