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PRESENTATION

Jessica Macomber Fye *- JPMorgan Chase & Co, Research Division - Analyst*

Hey, good afternoon, everyone. My name is Jess Fye. I'm the large cap biotech analyst at JPMorgan, and we're delighted to be continuing the conference today with Moderna.

Good news this year. We don't know how to switch rooms for Q&A. So Stéphane is going to give the presentation, and then we're going to go straight into Q&A after that. A couple of ways you can ask a question. There's mic runners in the room. So if you want to raise your hand, we'll try to get a mic to you or alternatively, you can submit a question electronically and I'll read it off the iPad up here.

So with that, let me pass it over to Moderna's CEO, Stéphane Bancel.

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

Thank you, Jess. Good afternoon, everybody, and thank you so much for joining us today. It's quite an impressive room for this presentation.

Before I start, let me remind you that we'll be making forward-looking statements, that investing in Moderna entails some risks that you can find on the SEC website or on our website.

So as you all know by now, mRNA is like software. As you know, computers use a binary system to code any piece of software where life across species on the planet uses a quaternary system to code for any protein. That makes mRNA an information molecule. And it's this belief and this understanding that led us 10 years ago to build this company.

We believe that the key main advantages of mRNA versus small or large molecule are very profound in what they can mean for patients and for creating value. The first thing that's very exciting to us is a very large product opportunity ahead of us, not only this year or next year, but in the next 10, 20 years, a very large white canvas to paint on.

Of course, we can do secreted protein like the biotech industry, but what excites us the most is we can do transmembrane protein, those protein on the membrane of the cell. We can do intracellular protein, including protein inside compartment of cells, like one of our rare disease program is inside the mitochondria that we're getting the protein in.

So a very large product opportunity. We can make very complex protein. In the transmembrane, you will see one of that is actually made of 5 protein for which we make 5 mRNA. That is actually in Phase III right now. So this is not science fiction. That's something we know how to do.

And we can combine mRNA. We have a program when we have 2, 3, 4, 5, 6 mRNAs in preclinical and up to 15 mRNAs in 1 dose. So the flexibility we have to do the right biology, to get a drug to work is very profound and very different from small or large molecules.

The other piece that has excited us since the beginning, and I think it excites me a lot having been in large pharma before, is the belief that we have -- that this technology will lead to higher probability of technical success of drugs getting to the clinic and drugs getting to market.

Why is that? It's because we always use the same chemistry. What we inject in the human body is the same for every product. So we believe this is going to drive a massive impact in change of probability of technical success versus the industry average that a lot of people are using to assess assets' chance to get to market.

The third piece that we believe that I think we have demonstrated a couple of times is the ability to go at a very different speed in terms of cycle time of development versus a small or large molecule. And why is that? It's because we always make the same product using the same processes.

While in large pharmaceuticals, you have to invent how to make the product every time the team in your labs have a cool new molecules, well, in our case, when the teams in the lab have a molecule they want to take to a clinic, it's the same manufacturing process than the other molecule. We're allowing us to grow really quickly sometime in 30, 60 days from a candidate to starting the clinical trial and filing an IND.

And last but not least, because we have the same manufacturing process for everything, we use the same factory with the same people in the same room using the same CapEx. Literally, 1 week, we can make a COVID-19 vaccine, and a week after, in the same room with the same machine with same people, we can make a flu vaccine or a rare disease drug or cardiology drug. So the flexibility that gives us, the efficiency of capital is really profound.

So based on those beliefs that we had 10 years ago, we set up a very different vision and strategy for how to build this mRNA company. We kind of threw the biotech playbook by the window because it was a different science.

So we believe it was not the right way to build an mRNA company when it was done for other technologies. And so the way we thought about it is that if we invest in technology, mRNA technology, delivery technology and for an application that we call modality, we can make the first drug work safely in human. Then the next drugs and the next, next drug in that same application is like copy and paste. Use the same chemistry for the mRNA, use the same lipid, the same route of administration, the same manufacturing process, you just change the order of the sequence and here you go again. And you could do that across many applications. And that's how we set up to build Moderna.

What is interesting is inventing a new application, a new modality is difficult, is time consuming and is expensive. Why? Because you have to figure out how to deliver the mRNA into the new cell type that you want to have a biological effect. That's hard.

And then you need to deal with immunity, how do you make sure that the immune system doesn't react in a way that you don't want about your product. And then, of course, all of the translation. But what is quite interesting in the last 10 years, but even more interesting now that we have $18 billion of cash and 4,000 people in the company is I believe that Moderna is uniquely positioned to continue to lead in the space of mRNA.

First, it's all we do. Two is we have critical mass in science. We have digitalized the company to allow speed, and we have the capital that we can invest in science. So what we have done over the last 10 years and as you can imagine, we've been a bit distracted with the pandemic. We have developed 7 modalities, 7 applications that you see on this slide that all have drugs in humans. We have many more applications or modalities that our teams are working on in a lab that we hope to be able to introduce if the science is positive.

I won't have time today to walk you through all of the programs, there's 48 of those, through all the modalities. I want to pick a few, and those I'm not going to cover are in the appendix of this deck that you can find on our website.

So let me start by the first modality, infectious disease vaccine. We think there's an incredible opportunity to have a massive impact on human health through mRNA technology for vaccines. There are more than 200 viruses documented by scientists that hurts human, 200. And there are vaccine against around 20 of those. That's a lot of white space.

So I won't have time to cover everything, but let me start by the big vaccines that we have a very active pipeline on. First, respiratory viruses. You are aware, of course, of SARS-CoV-2, of influenza. Now RSV is becoming more popular because it's doing a lot of damage. You can see on this slide some of the leading respiratory viruses that circulate in the U.S., in Europe, around the world every year. And you can see the red -- those viruses that do not have a vaccine approved on the market. And our vision for respiratory viruses is quite simple. We want to develop a vaccine against all

of those viruses. We want to combine them, so we don't need 3 or 4 shots every fall, and we want to adapt them to the variant circulating in the country where you live, not a single variant for the entire planet, which we believe some years doesn't make scientific sense.

So that's a bit the opportunity we're trying to address. Let me say a couple of words on COVID. So we reported this morning $18.4 billion of sales for the year. Those are, of course, at this stage unaudited. We confirm that we have at least $5 billion of contracts already signed or deferrals from '22 into '23 that would qualify kind of as a floor in terms of sales for the year.

In this $5 billion number, you have some countries like Canada, U.K. and so on. But this number assumes no sales in the U.S. And of course, we are working actively with the channels in the U.S. to provide the updated 2023 booster into U.S. pharmacy hospitals and doctors. No new contract in Europe is assumed in the $5 billion. No new contract in Japan, Middle East and many other parts of the world.

RSV. We're very excited about RSV because how much damage it does to the community every year. We've announced that our Phase III study, 36,000 participants, is fully enrolled. This is a Phase III study that's a registration study looking at safety and vaccine efficacy. We announced this morning that we crossed the number of cases, this is a case-driven study, 64 confirmed cases. The requirement was 42 for the first interim analysis. So we should expect it very soon, and I'm talking weeks, not months, the vaccine efficacy coming out of this.

On flu, we are running 2 Phase III studies: in the southern hemisphere, fully enrolled, looking at immunogenicity because some countries told us that we use that for an approval. And in northern hemisphere, efficacy study, 22,000 participants that could come as early as this winter, given the number of cases that has been happening across the world in the fall and this winter.

Let me now pivot to another family of viruses, latent viruses. Those are viruses that once in our body, never leave our bodies. And so they create short-term health care damage, but some of them creates very important and long-term damage. I won't go through the list. I don't have the time, but same thing on the right side, you can see all the vaccine -- all the viruses for which there's no vaccine on the market.

And so CMV is currently in Phase III. CMV, cytomegalovirus, is the #1 cause of birth defects in this country and around the world. 1 in 200 kids in the U.S. is born every year with CMV disease. The Phase III is 40% enrolled, and we are announcing that we are now also enrolling in Japan. We believe the CMV opportunity is $2 billion to $5 billion annual sales for this product given there's nothing on the market.

And as you can see, we believe that we can build a very important portfolio for patients and on the way to create value for investors across the different vaccines we have in the pipeline, CMV, EBV, herpes, VZV and also HIV. So that's a quick run by vaccines. I wish I could spend more time on vaccine. You guys can join us on our Vaccine Day in April to learn more.

So now modality number two, cancer vaccines. As many of you know, in December, we're very excited to share some positive data in our combination with KEYTRUDA with personalized cancer vaccine. This study was powered. The control arm was KEYTRUDA monotherapy. The other arm was Moderna personalized cancer vaccine plus KEYTRUDA. We are very delighted to show a hazard ratio of 0.56, meaning a 44% reduction in risk of recurrence or death versus getting KEYTRUDA monotherapy. You can see the p-value. It's the first time with mRNA that any company has shown you a randomized clinical study positive outcome. And as you know, cancer vaccines have been for the last couple of decades, a graveyard of candidates. And so we're very excited what this could mean for patients.

Because the mechanism is teaching T cell how to recognize epitopes from the cancer of every individualized patients, we think it's applicable to a lot of other tumor types. So we have our colleagues at Merck who are actively preparing a Phase III study that could start as early as this year and also planning several additional Phase IIIs in indications where KEYTRUDA monotherapy works. We have the same belief that we could improve the response versus KEYTRUDA alone, combining KEYTRUDA and one of our drugs. And we're going to be expanding and testing that technology in many, many tumor types and production is going much earlier in disease progression. So kind of watch this space, we're going to be investing aggressively in that space.

I'm skipping a couple modality for lack of time. Modality number five. We're very happy to announce this morning a very exciting program in cardiology for chronic heart failure. As you know, it's a massive medical program around the world. Just in the U.S., 1 million hospitalizations every year.

The molecule Relaxin is really interesting because it's a naturally occurring hormone in humans. It's used actually by pregnant women during pregnancy. And we believe that we can code that molecule to help people with heart failure. We've announced this morning that we've initiated a Phase I study in patients, and we'll share with you data as [we long over] this program that could move pretty quickly if the Phase I was positive.

Another important modality, modality number six, is rare genetic disease in the liver. There are a couple dozen rare genetic disease in the liver that cannot be drugged using small molecule or using recombinant. Why? Because the kids are missing a protein inside the hepatocyte of the liver. So we developed technology, IV injection going into the liver, delivering into what we believe is the hepatocytes, the mRNA molecule. We now have 6 patient years of experience on drugs. Some kids have been more than a year with dosage every 2 weeks.

It's generally well tolerated to date, and we're already seeing at low dose, a reduction in number of metabolic decompensation events, which the regulators have deemed is the endpoint for the pivotal study for this program. So we're monitoring this. We'll update data as we have more. But we are very excited because if this works, it will unleash the entire modality. Because as we all know, in rare genetic disease, the biology of risk is very, very low.

Another one that we are very excited about, which took a few years to make work in the labs, is the ability to deliver inhaled mRNA to patients. So we partnered with our colleagues in Boston Vertex to work on developing a CFTR mRNA program, coding for the entire CFTR gene to help those kids that don't respond to the standard treatment where Vertex has a massive impact on so many lives.

But there are still several thousand kids that don't respond to treatment. So what we believe is that if we are able to give them a full-length CFTR protein in their lungs, we could basically restore their lung functions.

And so we developed that technology. We're very excited that the R&D was opened by the FDA, that this got a Fast Track designation. And this morning, our colleagues at Vertex announced that we've already started dosing in human, in patients, of course. So this should be able to go very quickly because those kids have no hope, they have no option.

And if you think about it, if it works in this application, then we can open a brand-new space, a new modality in lung disease. Think about all of the lung disease that we could go after inhaled mRNA. That is extremely exciting for us.

So this is a typical slide we use to just give you a quick summary of where we are as of January 2023. I won't read everything. Just to tell you, we have now 48 programs in development, 48. The company is close to 4,000 people, and there are budget calls for adding 2,000 employees this year because we are scaling research, we're scaling development, we're scaling manufacturing and of course, we're scaling commercial.

As of the end of the year, we had around $18 billion of cash. So how do we intend to deploy that capital? Our #1 priority, and we have been saying that for a couple of years, is to invest in the company. We spent 10 years to develop a platform that could scale. One of the biggest challenge of pharmaceutical companies is what is next in your pipeline. We have an information-based molecule, and we build a platform around it. And so with the management team and the Board of Directors, we understand our science. We believe our ability to scale. And so what we announced this morning is the Board-approved budget for 2023, it's actually $4.4 billion of R&D investments.

Many Phase IIIs, as I said in cancer vaccine, we have our colleagues at Merck, which is a 50-50 cost share and profit share. We're going to be very aggressive. We've also announced we bought a priority review voucher, which now makes -- we have 2 of them. And we have 2 Phase III that should read out, flu and RSV, this quarter. So those 2 can be handy to be able to move very quickly towards approval if the results are positive.

In terms of partnership, we do not believe we are on everything, being able to the best science in the world. We believe there's amazing science happening outside our walls of our labs. And so we want to tap that technology. And so what we have done last year, you can see the top line, Metagenomi, Carisma, and already this year, actually, last week, announcing 2 new partnership, an acquisition in Japan and also a licensing agreement.

What are we trying to do with those partnerships? We're trying to expand the size of our mRNA operating system. We want to provide our therapeutic area with more and more technologies to be able to do more and more drugs using mRNA. We believe there are so many things that we are still learning and exploring to keep expanding and expanding and expanding the mRNA operating system.

OriCiro is a good example, small private company in Japan with amazing new technology. They figured out how to make plasmid, which is the raw material to all the mRNA we make, without using E. coli. Synthetic, cell-free, enzymatic reaction, huge impact in terms of speed, scalability and purity of products. That will help us across the company. Using that technology, we can go faster to the clinic for personalized cancer vaccine, which could have an impact on efficacy and more people responding because they are dying of their cancer. It can help us in the labs to go faster from ID to data, to just expand the mRNA operating system faster to get into the clinic faster.

Think about when there's a new variant. The FDA told us on June 28, they wanted a BA.5 Omicron variant. It was in pharmacy on September 2. But we spent all of July waiting for the plasmids, GMP plasmids. This technology will allow us to shut that time by maybe half. So that's going to mean a lot of impact for patients.

And then the excess cash, we will return to shareholders. So we already announced 2 share buybacks. In 2022, we bought for $3.3 billion of stock at an average price of $143. There's still $2.8 billion of remaining capacity in the current plan. And the Board will continue to review as appropriate the use of cash between investing in the company, which is our #1 priority, doing partnership to expand the OS and the access to return to our shareholders.

What is exciting for me is that the company is accelerating because the biopharmaceutical world is an analog world where companies have drugs that are all different. But in our case, we have a platform. And so if you look at some of the historical data, at the end of 2018, no commercial product, of course, 21 products in development, mostly early stage. The end of 2020, commercial product, 25 products, moving to a later stage. 2022 -- because in 2020, we were kind of pretty busy with the pandemic. 2022, 48 programs in development, 4 program in Phase III, 9 program in Phase II. So you can see our pipeline is expanding into new modalities and is accelerating because we have the capital to do so.

So if we invest $4.5 billion in R&D this year, what do you think it's going to look like in 2, 3, 4 years from now? I want to be quick on my slide. Our R&D budget in 2019 was less than $500 million. So if you think about it, this picture was generated with much lower R&D budget than where we are now. $4.5 billion is around 10x. There are the investments we're going to do in '23 versus what we did in 2019. So this is going to drive a lot of change in our pipeline and, I think, a big impact on patients.

Because of where the company is and the growth of the company is, we spent quite some time in the last few months to think about where are we heading. What you see on this slide is our original mission, the one we set up when we started the company. Our goal 10 years ago was to figure out how to make mRNA work because we are convinced that if we could make one drug work because mRNA is information, we could do a lot of drugs. And what we could do for society and the patient over the next 5, 10, 20, 30 years could be transformational. Potentially, as big, if not larger, than what recombinant as an industry has done over the last 40 years.

But where we are today, we know mRNA works. So we thought about what's our next 10 years journey, what's our mission? What should drive us in the morning? And what you see here is what we think is very important to who we are and what we want to become, which is, as a team, we want to deliver the greatest possible impact to people through mRNA medicine. What we're optimizing for is the maximum impact we can have in the next 5, 10, 20 years on the world. Thanks to this amazing science.

I hope you will join us for some of the key events this year. And I would like to thank you for your attention. I'll be happy just to take any questions. Thank you.

QUESTIONS AND ANSWERS

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

Great. Thanks for that presentation. Just maybe starting out with a bigger picture question. Can you talk about how you think about the future as we move toward treating COVID as an endemic disease and as the U.S. shifts towards a commercial model?

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

Sure. So like everybody, I have never managed a transition from pandemic to endemic. So we are running as we go. But we're trying to use other viruses, other disease to kind of help us think about it, at least directionally. We think that flu is a pretty good model for where we think things will end up. The need to update the product regularly based on the biology, potentially different booster in different geographies, which we can do.

And we're trying to really help us by even building plants around the world. I don't have to talk about it in this presentation, but we're building a plant in Canada, we're building a plant in Melbourne, we're building a plant in the U.K., where we've had 10 years agreements with those governments, 10-year supply agreement that have been signed to basically procure from Moderna respiratory vaccine that we can adapt with the local authorities to what they want for their people.

And so I think from the 50 and -- 50 years old and above, people that have immunocompromised, seriously sick, the need for an annual booster is going to be important. But I don't think that's the only population of -- the example I use is I've done a flu shot over the last 20 years. We provided the flu shot at Moderna since the last 10 years every year as a benefit like many companies do. Have I taken a flu shot -- I'm 50 now so -- since I was 30 because I thought I was gonna be hospitalized or dying? No. Because they don't want to be sick, they want to give it to somebody else. And I think a lot of people are going to do that as well. Do I believe everybody is going to do it? No. But I think if you look at the 50-plus and people who are high risk and people who just want to be protected, I think it's going to be an interesting market in terms of size.

And then I think as we get more and more combination, we're trying to work on COVID plus flu, COVID plus flu plus RSV because nobody really likes needles so much. When we talk to payers, they are very worried, as we get into a COVID plus flu and sooner pretty, plus RSV, is how we're going to ensure compliance. Because what they want is if those vaccine exists, they want people to use them, especially people that are high risk that might end up in hospitals.

And so through the discussions we're having with payers, both private payers but also health ministers and so on, we believe that there is a very, very important demand out there for combinatory vaccines. And that's exactly where, as you know, we are going in terms of pipeline and strategy. So I think combinations and I think the customization of products by geography is going to be driving a big competitive advantage.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

Okay. So you touched on this a little bit, but you've got some other viral vaccines in development where there is a bunch of competition and some other ones where there isn't a bunch of competition. So how do you decide where to go? Like what's your kind of overarching infectious kind of vaccine strategy?

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

Sure. So let me start by the easy ones. If there is a good vaccine out there, we most probably are not going to do anything. So a good example is hepatitis. There's a good vaccine for hep A and hep B. We have never even talked about should we do a hep A or hep B vaccine because we don't see the medical need and how much value we could bring. And given all the things we could do, we'd rather do something else with our talent and our capital.

Respiratory is different because, first, we believe we can get a much higher efficacy on flu. We don't think we got that done on the 1010, the first flu program because it was not designed for that. It was designed to be noninferior to commercial flu products to go to the market quickly because

we believe a COVID plus flu -- COVID with -- Moderna's product has shown the best protection against hospitalization. And if we have a noninferior flu vaccine, we think that we will provide a lot of value to the health care system. And so that's what we want to do first.

But if you think about flu, there's a lot of things that can be done with flu with mRNA to increase the efficacy because, as we all know, the current vaccines don't have a great efficacy. We can do HA antigen and NA antigens to actually improve, we believe, the efficacy of a vaccine. H3 strain is the most important one. Why? It drives 90% of hospitalization.

So why only pick one H3 strain, which over technology are constrained to because they cannot do more. What about doing 2 or 3 H3 strain in a single dose? So you look at the different strains circulating around the world because it's really hard to guess where the virus is going to be in a few months when you -- when there were vaccines in pharmacies.

And so we think we can use the technology in quite an interesting way to develop different products. I've even been talking to a country that I won't mention because it's a discussion with sovereign whose public health experts and health minister say, hey, should we put pandemic strain of flu in the flu product for our country? Think about like an H5. And then the year after, an H7 and the -- an 10 because you could create some herd immunity so that if there is a new pandemic with flu, these types of coronaviruses, you could have a bit of herd immunity. And you could rotate that every year. So there's a lot of ideas that you could have using mRNA. If you design the product a bit like it's done in the tech world, which is start by the problem you're trying to solve, and design the product backwards.

In biopharma, people have one molecule and they're trying to do the best they can with that molecule and to find where it could be used. But the way we design drugs is very different. We start with the medical program, the science, and we move backwards to say, what do we need to do in terms of components? So the product has a high chance of working like CMV.

Most pharma companies doing vaccine have tried the CMV vaccine because it has been the #1 priority of the National Academy of Sciences for 20 years. And so vaccine went into Phase II, but they failed because efficacy was too low. Why? They only covered for the gB antigen. But it is well known by scientists that the virus can also get into human cells. They have a pentamer. So it was believed in the industry that if you don't have a pentamer, you have no chance, but a lot of pharma company -- because they only could do the gB because the pentamer, as the name says, it's 5 proteins that have to come together. So good luck with a recombinant to do that. But they still went into the clinic. This are type of things we will not do because we have so many other things we can do, where we think the science makes sense to increase the chance of a drug to get to market.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

Okay. We have a couple of questions from the audience here. Can you talk about how Moderna thinks about original antigenics in or immune priming with respect to COVID?

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

Okay. So I think the question is really around the different populations because what I think is quite unique about this virus versus other virus that we are dealing with in the respiratory space is most of us, and I think I can say all of us in this room have never seen the virus as young people, which is why I think people who think that the need for boosting in the elderly won't be there. I just don't understand the science.

We believe that because we have not seen, again, the older ones in the room, we have not seen this virus in early years of life, especially not teenager years with a very strong immune system and memory, that the need for boosting the subjects are going to be really important.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

Okay. The next one here is -- it's kind of a statement and a question. Moderna's technologies can change how we do gene editing. You established a great collaboration with Metagenomi. Can you tell us more about how that's going and what your plans are to go to tissues beyond the liver with LNPs or other delivery systems?

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

Sure. So I think there's 2 questions in there. First is about increasing the application of mRNA. So as you saw, the 7 modalities use different lipid or different route of administration, like the lung, the liver and so on. So we're investing large amounts of money to invent new modalities to go to new cell types. And we can do that for other using mRNA to code for protein as a therapeutics or going to the part of the question around gene editing. We can use the money to code for an enzyme that's going to do gene editing.

While we have all been excited about CRISPR-Cas9 system -- because I'm not aware of any technology that human has touched where the first version of the technology is the best one. We think that it's just the beginning of a very exciting time for science and biology to find different gene editing systems. That's where kind of Metagenomi comes into play where we want to figure out for different cell types, potentially for different jobs to be done by the enzyme where you might want to use different enzymes.

We believe that one thing to do -- one tool to do everything might not how you build a house. And so we are very long in genomics. We have a group that soon is going to be up to 200 people. They are leveraging the entire Moderna infrastructure. So they design mRNA for new gene editing enzymes, and it goes to the same robot that makes everything else that we use for the portfolio. And we can move things to the clinic also very quickly because the idea here is the same, is using the same delivery system using the same mRNA just to do gene editing versus just making a human protein.

So we think that if you look at the level of investments we are making in gene editing and the infrastructure we have at Moderna in research, development and GMP manufacturing, that potentially in a couple of years from now, we're going to be actually a very large player in gene editing.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

Maybe switching to PCV. Obviously, we got the encouraging top line results. Can you talk a little bit about where you see this product going, whether it's what tumor types or what other settings?

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

Sure. So given the data and how we think it's a very profound impact -- and as you know, the study was powered and randomized and kind of where the p-value and hazard ratios are and so on. We and our colleagues at Merck are really excited about the technology. We've shown and presented ASCO in 2019 I think, '18 and '19, I think, the fact that we were able to get T cells that did not recognize epitopes coding in our products by taking the blood of cancer patients before dosing our product and taking their blood after several injection and showing that then the T cells recognize the epitope we know we coded in our products. So we think that were a mechanism of action.

Now we have clinical outcome. And so we believe this should be applicable to a lot of tumor types across the board. We're going to, of course, start where KEYTRUDA works. But we've had discussions with our colleagues at Merck to say what type of tumors where actually KEYTRUDA did not work, where it might make sense to go back because maybe by combining personalized cancer vaccine to KEYTRUDA, you might get the immune system to the right place where you can have a clinical impact that is beneficial to patients.

And then we want to also go earlier in disease. We're going to want to go later in disease. Could you think -- and now I'm kind of brainstorming for a minute, some forward-looking statements. Could you -- for example, with the improvements in liquid biopsy, could you see a world where you try this combining with products like GRAIL and others, where you basically through blood work, figure out some mutation that you coded in the vaccine that you basically give very early on? Because we really believe, given what is known about immunology, that getting younger patient and much earlier in disease should lead to better outcome because of what happens to the immune system through the disease progression. And so we're going to be creative. We're going to be bold in terms of how many things we do.

The great thing with Merck, as they have shown the world with KEYTRUDA, they were not shy to try a lot of different studies at the same time. I think that experience and also what's happening with the product patent expiry that they have on their hand and our belief in the science of mRNA

and the balance sheet that we have. I think you have 2 companies -- and I spoke to Rob Davis, the CEO of Merck, several times in the last few months. We are both very eager to be really bold about what we think this can do for patients and, as a consequence, creating value for shareholders.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

So I think you mentioned you have enough events in the RSV trial to do your first interim?

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

First interim.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

What are the kind of scenarios here if you hit or don't hit on the first interim? What happens next?

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

Sure. So if we don't hit on the first interim, then we keep going. The study is not going anywhere and will be for quite a while to monitor people for much more than the 12 months required for filing. Because of how statistics works, it's not because we missed the first interim that necessarily we have a bad efficacy. And if we hit it and we have vaccine efficacy, I think the thing we're going to be looking at is, first, what's the efficacy against disease because the vaccine that have published data so far I think have a very good 80-ish percent protection against hospitalization. But I think -- I hope one could do better on the efficacy against disease because anybody who gets a vaccine will hope, of course, not to get hospitalized but would also hope not to get sick. So I think a prevention of disease is going to be important.

And then it's a tolerability profile. One of the vaccine that has already got data out there is using a pretty strong adjuvant. And so those are the 3 things I think we're going to be looking at: VE against severe disease, VE against mild disease and tolerability.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

And that comes very soon?

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

That should come very soon. [I got to say] days or weeks, not months. I mean the team is analyzing over data and so on. So when everything is good and QC-ed, we will release it.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

Okay. You've also got a number of efforts ongoing in rare diseases in addition to vaccines, in addition to oncology. Where do rare diseases fit in kind of Moderna's strategy?

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

I think it goes back to the same thing, which is we want to use this technology to help patients. And if you think about those rare genetic diseases in the liver, those kids and those parents have no hope. They have an enzyme that you and I have that they're missing. And every time they just

get runny nose, they get a viral infection or something, the parents rush to the hospital, their kids in the ICU, and they might lose their children. That's the standard of care today. They try food diet and other things to minimize the risk, but every decomposition event could lead to death for those children. And because of some of those disease leads very high level of acid, you have a lot of brain damage every time you have an incident.

And so the way it fits the strategy is we can help patients because the biology of risk on rare disease is very low. If you think about cancer or HIV, it's through the roof, but rare genetic disease that have single mutation have pretty low biology risk. And if we can do it once to get mRNA into the hepatocyte of a liver, then the next time we just change the sequence and we go again.

So could you get a couple of thousand drugs? Some might be over $1 billion, some might be $500 million, some might be $200 million or $400 million because of the size of the market. But if you don't need to build any plant for it, if the drugs are going to be developed very quickly, if once you're in the market, it's going to be very hard for anybody else to come behind us in terms of doing a study because it will be unethical to take kids out of a drug working. And until genomics really works really well, you might have those kids forever and the newborn kids with those disease.

And as we work on genomics, we might be able to go back to offer parents and doctors and the patients ever repeat dosing like every 2 weeks like enzyme replacement therapy using mRNA to code the protein like what we did today and/or propose a gene editing solution because we know how to get into the same cell type. So that's a bit how we see the strategy. But like you see Vertex, we talked about it, going back with an mRNA solution to treat the patients that they could not treat using the current products. We're trying to really obsess about the patients and the families and say, how do we help them and how do we create the right product or the right products for each disease?

And then we think we'll create value on our way because, again, small clinical trials that are pretty quick, no plants to build. So if you think about just the economics of rare disease for Moderna, it's actually extremely attractive.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

Okay. Great. Well, we're out of time, so we'll leave it there. Thank you.

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

Thank you.
