Q4 2020 Earnings Call

Company Participants

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

Other Participants

- Cory Kasimov, Analyst
- Gena Wang, Analyst
- Geoff Meacham, Analyst
- Hartaj Singh, Analyst
- Mani Foroohar, Analyst
- Matthew Harrison, Analyst
- Michael Yee, Analyst
- Salveen Richter, Analyst
- Simon Baker, Analyst
- Ted Tenthoff, Analyst

Presentation

Operator

Good morning and welcome to Moderna's Fourth Quarter 2020 conference call.

At this time, all participants are in a listen-only mode. Following the formal remarks, we will open the call up for your questions. Please be advised that the call is being recorded.

At this time, I would like to turn the call over to Lavina Talukdar, Head of Investor Relations at Moderna. Please proceed.

Lavina Talukdar {BIO 19691239 <GO>}

Thank you, operator.

Good morning everyone and thank you for joining us on today's call to discuss Moderna's fourth quarter and full-year 2020 financial results and business update. 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 CEO; David Meline, our CFO; Stephen Hoge, our President; and Tal Zaks, our Chief Medical 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 two of the accompanying presentation and our SEC filings for important risk factors that could cause our actual performance and results to differ materially from those expressed or implied in these forward-looking statements.

We undertake no obligation to update or revise the information provided on this call as a result of new information or future results or developments. On Slide 3, please see the important indication in safety information for our COVID-19 vaccine which has been authorized for emergency use in the United States and many other countries around the world.

With that, 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. Thank you for taking the time to join our Q4 2020 call. For the call, we proposed to start by looking back to fiscal year 2020 and then looking to fiscal year 2021. For fiscal year 2020. I will share a few slides to summarize the key elements of the year before David shares with you the 2020 financials and also how we think about 2021 financial framework.

For fiscal year 2021, I wish our business objectives and why we are so excited for 2021 and the Inpixon going this year we will present in our history. Given we start with an update on our approach to variants of concern and then Tal will provide on the date of our clinical pipeline. 2020 was a historic year for Moderna. We started in January as an early stage development company. By the end of July, we had become a late-stage development company and by December, we had positive results from our Phase three COVE study of our COVID-19 vaccine showing efficacy around 95%.

Our COVID-19 Vaccine was approved by the FDA and Canada Health in mid-December and we shipped almost trillion doses to the US government and the Canadian governments by year-end. We laid the groundwork for global organization adding commercial subsidiaries in 8 countries, 8 countries. By year end, we have signed $11.7 billion of advanced purchase agreement for the COVID vaccine. A team of internal (inaudible) members did all that, and we also continued to invest in science to improve performance of our MRNA platform, and we are still advancing programs in development across 5 therapeutic areas.

And we did it without the large global pharmaceutical partner. The Moderna team executed swiftly and superbly in carrying out a complicated Phase 3 study what actually did remarkable diversity. The Moderna team secured the authorization of the COVID-19 vaccine by regulators. Our team built out our manufacturing capacity scaling up across many manufacturing processes.; BARDA, Lonza, ROVI, and Catalent, and shipped close to 80 million doses buyout. For context, we had met less than 100,000 doses of medicine in 2019.

This was roughly a 200 times increase in twelve months, and we are on our way to produce as many as 1 billion doses in 2021 and more in 2022. In 2019, we have no price product. We had negative cash flows from operations every quarter, and we anticipated needing multiple (inaudible) over at least 5 years until CMV will produce significant revenues for Moderna to breakeven in term of cash flows and become a self-sustaining company.

In 2020, we had first product authorized, and we'll go first product revenues in the last 2 weeks of Q4. We had 2 quarters of positive cash flows from operation. We ended the year with a strong balance sheet, and we've cash generation in 2 quarters. Moderna has been changed forever. Moderna has been changing in a profound way. Moderna is now a commercial company with subsidiaries in 8 countries and the direct presence in many more for commercial distributors and partners. MRNA is the new commercial molecule.

We have a powerful platform, and this is just the beginning. We have a scalable platform due to our investment in IT, robotics, and AI over the last 7 years. We have an amazing team as you witnessed by what the team accomplished in 12 soft notes of 2020. And we have a capital to invest and scale.

On slide 6, you have the summary of the countries in which we received emergency use formulation of conditional approvals and all the stuff submission that we need. On slide 7, you get the sense for the commercial infrastructure that we built. For context, in May of 2020, Moderna did not have a single employee dedicated to commercial activities. We closed the year with 8 commercial subsidiaries and an equitable commercial team and commercial partners. We now have commercial operations in the US, in Canada, and in Europe in the 5 largest markets; Germany, France, Italy, Spain and the UK. We established one in Switzerland where we have both commercial capabilities, we have a Swiss market as well as manufacturing for geographies outside the US with our partner Lonza, and the support teams that we need to finance, HR, digital, and (inaudible).

We are partnered with Medison in Isreal and with Takeda in Japan. If you step back and think about it, this commercial network, which we started building and will expand in 2021 is an incredible asset for the entire Moderna pipeline. We now have the infrastructure to commercialize our overall products. These market on the slide of some of the largest market in the world. So by the commercial network for the launch of our COVID-19 Vaccine and deciding not to partner, we have actually financed in the commercial network for all of our programs.

We have become a fully integrated company and in 12 months, proved that we are capable of any complex S2 studies, scaling our manufacturing to commercial level, making 100 of millions of doses per year and building on our commercial network. As I said, the Moderna team did an amazing job in 2020. On Slide 8, you get a glimpse of what Moderna looks like in February 2021. While most people in the world think of Moderna as a COVID-19 vaccine company, it is just the first product that we are launching. We have a platform and the molecular mRNA is an information molecule, it is just the beginning. We're going to soon start a Phase III study for vaccine against CMV (Cytomegalovirus), the number one cause of birth defects. There is no approved CMV vaccine on the market. The pharma industry has tried for around 20 years to make a vaccine against CMV, this is a complex virus, a vaccine (inaudible) from a complex protein COVID pandemic. We believe that CMV vaccine will present commercial annual peak sales between $2 billions and $5 billions. We are preprogramming Phase II of personalized cancer vaccine in melanoma, OX40 ligand in ovarian cancer, and they just injected in patients in (inaudible) to revascularize the heart with new blood vessels.

We have had 12 positive Phase 1 readouts. In addition to our COVID-19 vaccine, we have 80 infectious disease vaccine candidates or for first-in-class vaccine like against CMV, or what we believe could be a best-in-class vaccine that we've influenza, but we also have a remarkable therapeutic for pipeline. We've candidate for therapeutic in immuno-oncology with 5 medicines in the clinic, 4 in neurology program, 2 cardiology, and 2 autoimmune disease programs. If you think about it, Moderna is scaling up the fall in case of death by disease area; infectious disease, cancer, cardiovascular disease, and autoimmune disease. The total addressable market is very low. We are not a COVID-19 vaccine company.

We're investing in science and leveraging our scalable platform to take more candidates from our research labs, so clinical development soon, so stay tuned for that.

We announced yesterday that we are increasing our base manufacturing plant of the number of COVID-19 dose we will produce in fiscal year 2021 from 600 million to 700 million doses given the strong stop of our US operation an initial ramp of all outside the US operation. Our team is still working hard to get us up to $1 billion for fiscal year 2021.

Now let me turn to David for Q4 and fiscal year 2021 financial framework. David?

David Meline {BIO 6397419 <GO>}

Okay. Thank you, Stephane. Before reviewing the financial section of the slide deck, I want to comment on the approach we take in sharing this information. This starts with the thee C's, these being clear, complete, and comprehensible. Today, we are presenting our results primarily on a US GAAP basis. And at an individual item level in some cases, we also provide additional detail to provide greater clarity on underlying trends and to facilitate period-over-period comparisons in line with those 3-C goal.

Reflecting the continued uncertainties related to the course of the evolving pandemic along with the many challenges and opportunities we face as a newly globalizing

commercial company, we also seek to avoid implying an unrealistic level of precision concerning future financial projections in the face of a range of outcomes. With this background, we are providing today the analysis of actual 2020 results along with a view of key drivers of the financial framework going forward. We will continue to update and refine this information as business evolves.

Turning to slide 10, I want to briefly remind you about some key accounting changes which we presented on this slide in our Q3 call in October. As a result of the successful transition to a commercial company following the emergency use authorization by the FDA and Health Canada in December 2020, we began to record product sales, we also began to capitalize inventory based on the expectation of these costs would be recoverable through commercialization of our COVID-19 vaccine as opposed to expensing costs directly to R&D in the period incurred. And we also began to capitalize purchases of property and equipment and long-term lease assets as opposed to expensing costs in the period incurred due to the lack of alternative views.

With this context, let me turn now the slide number 11. Total revenue was $571 million for Q4 2020 compared to $14 million for the same period in 2019. Total revenue was $803 million for the full year 2020, compared to $60 million in the prior year. Following the authorization for emergency use by the FDA and Health Canada in December of our COVID-19 vaccine, we generated our first ever product sales.

For 2020, we recognized $200 million of product sales for COVID-19 vaccine all in late December. Additionally grant and collaboration revenue increased to $371 million in Q4 and $603 million for the full year, primarily due to increases in grant revenue from BARDA to accelerate development of our COVID-19 vaccine.

Now turning to cost of sales, we began capitalizing our COVID-19 vaccine inventory costs in December starting after the vaccine was first authorized based upon our expectation that these costs would be recoverable through commercialization of the vaccine. Prior to the authorization of our COVID-19 vaccine, inventory costs were recorded as research and development expenses in the period incurred. We have spend $242 million of prelaunch inventory costs in 2020, hence our cost of sales were only $8 million in 2020 comprised primarily of third-party royalties. If inventory sold during 2020 was valued at cost, our cost of sales for 2020 would have been $62 million or 31% of our product sales.

Research and development expenses were $759 million for Q4 2020 compared to $118 million for the same period in 2019. Research and development expenses were $1.37 billion for the full year 2020 compared to $496 million in the prior year. The increases for both 3 and 12-month periods in 2020 were mainly due to increased COVID-19 vaccine clinical development activities, headcount increases, prelaunch inventory buildup, and expenses associated with the equipment and leased facilities that were deemed to have no alternative use at the acquisition of such equipment.

Selling, general and administration expenses were $79 million for Q4 2020 compared to $26 million for the same period in 2019. Expenses were $188 million for the full year 2020 compared to $110 million in the prior year. The increases for both periods were mainly

driven by increases in personnel outside services and start-up costs associated with preparation for commercialization of our COVID-19 vaccine globally. We recorded a net loss of $272 million for Q4 2020 compared to $123 million in the same period in 2019 and $747 million for the full year 2020 compared to $514 million in the prior year.

Turning to selected cash flow information on page 12, we ended Q4 2020 with cash and investments of $5.25 billion compared to $3.97 billion at the end of Q3. The increase is primarily driven by $1.7 billion of customer deposits received in the fourth quarter for supply of our COVID-19 vaccine. 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 the cash deposits received related to supply agreements for COVID-19 vaccine.

Net cash provided by operating activities was $2.03 billion for the 12 months ended December 2020 compared to net cash used of $459 million for the same period in 2019. The reversal from cash used to cash provided by operating activities is driven by total customer deposits. Cash used for purchases of capitalized property and equipment was $67 million for the full year 2020 compared to $32 million in 2019.

Before looking forward to 2021, let me summarize a few areas from our 2020 results that are important to keep in mind when modeling 2021 financial performance. Starting with research and development and SG&A expenses shown on the top left quadrant of Slide 13. Prior to the authorization for emergency use by the FDA and Health Canada, as a pre-commercial research stage company, Moderna expensed all cost related to the production of inventory as well as cost per property and equipment and lease expenses for current and some future contract manufacturing activities due to lack of alternative use. Adjusting for these items, which in the future would be capitalized and expensed as cost of sales, the underlying R&D and SG&A expense run rate for Q4 2020 was $0.5 billion for the quarter.

Turning to the upper right quadrant of Slide 13, cost of sales includes the cost of goods manufactured logistics and warehousing costs as well as third-party royalty costs. The reported expense in Q4 of $8 million reflects the fact that we expensed all inventory related costs until authorization of our COVID-19 vaccine. If valued at cost, our actual cost of sales, including initial ramp-up costs would have been $62 million or 31% of product sales. The cash and investment balance reported as of December 31 was $5.25 billion, $2.8 billion of which related to cash deposits from customers for future supply over COVID-19 vaccine.

Lastly, let me comment on certain tax-related items. The significant investments in our research and development and startup activities to develop the MRNA platform over the last decade has resulted in a net operating loss carry-forward, with the balance as of December 31, 2020 of $2.3 billion, up from $1 billion at year-end 2019. As of December 31, we maintained a full valuation allowance against our deferred tax assets related to these loss carry-forwards.

We will continue to monitor the valuation allowance as we progress through 2021 and expect to utilize our loss carryforwards.

With this context, let me now move to considerations through 2021 starting with an overview of advanced purchase agreements for COVID-19 vaccine on slide 14. We have disclosed advanced purchase agreements to supply our COVID-19 vaccine to 40 countries through the end of 2021, including the US government for 300 million doses with options for an additional 200 million doses. The European for 310 million with an option for an additional 150 million doses in 2022, plus 10 other countries, including Japan, Canada, and South Korea with announced doses totaling 186 million.

We are thankful for the trust the governments around the world have placed in us to deliver a vaccine for their countries. All these agreements contain provisions for deposits and have contributed to our balance of deposits of $2.8 billion at year-end 2020. Negotiations with other countries are also ongoing including with COVAX.

Turning now to the 2021 financial framework on slide 15, already signed APA agreements were expect to delivery in 2021 reflect a total of $18.4 billion in anticipated product sales. Based on continuous progress to ramp up, available supply capacity in our network. We have raised the lower end of our global manufacturing plan for 2021 from 600 million to 700 million doses at the 100 microgram dose level. Manufacturing is still working to supply up to a billion doses for 2021. Further, we expect a range of related of released doses in Q1 2021 of 100 to 125 million doses and 200 to 250 million doses in the second quarter.

Our total cost of sales, includes the cost of manufacturing, logistics and warehousing, and third party royalties as discussed previously. For 2021, we currently modelled, total cost of sales as a percent of product sales to be approximately percent for the full year with some variation quarter by quarter, largely driven by the average selling price. We also expect Q1 reported cost of sales in percent of product sales to be in line with the full year average including the benefit from the remaining 0 cost prelaunch inventory in Q1.

Now, let me comment on planned R&D and SG&A expenses. The underlying Q4 2020 expense run rate adjusted for transitional items as discussed on slide 13 was approximately $0.5 billion. We currently expect our quarterly reported expenses to increase on a continuous basis through 2021 compared to the Q4 2020 adjusted run rate.

In Q1, we expect an increase in the low double-digit percentage range relative to the adjusted Q4 2020 expense run rate of $0.5 billion. We will provide additional updates going forward as our global business rapidly expands. I would also like to comment on how we think about modeling our tax rate. In 2021, Moderna will transition to tax-paying status as we deliver on our COVID-19 vaccine contracts to customers. As a US-based company, we start with the statutory 21% tax rate. This is impacted by global sales mix to the extent that non-US rates are generally lower than in the US and by recovery against our prior accumulated losses of over $2 billion.

As we start the year, we expect the all in 2021 tax rate to be in the mid-teen percentage level on an ongoing basis, including in the first quarter. We will update this view as their book of business evolves further.

Lastly, regarding capital investments, we currently planned capital investment in the amount of $350 million to $400 million for 2021. Roughly half of the investment is to further expand our COVID-19 vaccine supply capability, including supply capacity up to 1.4 billion doses at the 100 microgram level with the balance of planned capital investments to expand our technical development, clinical manufacturing as well as our other facility footprint.

This concludes my remarks concerning the financial performance and I turn the call back to Stephane.

Stephane Bancel {BIO 15174250 <GO>}

Thank you, David. Let me now discuss 2021 on slide 17. We are seeing in February, the Moderna COVID-19 vaccine is not authorized in 37 countries, and our team is continuing to engage weekly ourselves in new geographies like Japan, Taiwan, the Philippines, and more. We are also well on the way in the rolling submission process with WHO which will be key for low-income countries access we are COVAX and UNICEF if we get a partnership done.

We are committed to our principles of global access to our new class of medicines while we work on that that the need for scale up manufacturing operations have led to supply going to the US, Europe, and other countries. We are working with COVAX to provide low cost vaccines to the poorest countries, and look forward to supplying or vaccines for COVAX Gavi and becoming a company that will be part of the global health infrastructure for many years to come. UNICEF is a procurement arm of COVAX. On slide 18, as I shared you might 20-20 shareholder letter, which we posted publicly on January, and which you can access on our block if you have not read it, I believe that's 2021 is going to be the most important inflection year in Moderna's history. You can see very evolution of the company over 2019, 2020, and 2021 on this slide over a few dimensions, but to me, the reason I say that 2021 is the most important inflection year in the company's history is that we are not the same company.

As I've told our employees (inaudible), I almost wished I could change the company name where we totally understand the magnitude of the change. We used to believe that MRNA vaccine could be authorized and become commercial. We used to have a negative cash flows from operation each quarter since our founding in 2010. We used to have to raise additional capital regularly and what we needed to do that for another 5 plus year until CMV, we get the company's cash flow breakeven, but we have been through an incredible period, this is not the same company.

Now we know that the MRNA vaccine can be authorizing and become commercial. Now, we are positive cash flows from operations for 2 quarters in a row already. So now we are going to double down on our investment in science, in process development, in manufacturing, in IT, in robotics, in AI to scale our company. I believe that in business, there is a drastic difference between believing in an outcome and having negative cash flow ratios, knowing an outcome, and having positive cash flow. Our appetite and the liability to invest has been transformed. We are not the same company now that were in the last 10 years. Our thinking is going to be much more expansive.

On slide 19, as David shared a moment ago, we have as of yesterday already $18.4 billion of signed advance purchase agreement for fiscal years 2021 deliveries. We still have multiple discussions ongoing about additional APAS for 20-21, but these have not been signed yet. So we are not counted in the $18.4 billion. We'll update you each quarter about the signed APAS for our fiscal year 2021, as we report cell recognized with the shipment of our COVID-19 vaccine. We increased our manufacturing in base plan for the year to 700 million doses and are working hard to get to a billion. We are working with COVAX and it is procurement, I mean is there to maximize the availability of a vaccine around the world.

Let me now turn to slide 20, to talk about 2022 manufacturing capacity. We announced last night after the market closed, that several factors have led us to decide to add more manufacturing capacity. First, many governments have been sending us that they now see 2 classes of COVID-19 vaccine based on efficacy, and they would like Moderna vaccine given its high efficacy.

Second, variants, governments and public health leaders around the world are concerned about the emergence of several variants. They have been very clear about it and some of them are talking to request options for 2022. With the start first season soon in the southern hemisphere, we were large population of the world and we were population of immune compromised patients like HIV-positive patients, wherein daily the governments around the world and the COVID teams worried that boosting people with variant will be an important strategy over the next couple of years to get these virus under control.

So we decided to add manufacturing capacity. We have communicated previously that the capacity for 2022 given the ramp in 2021 will be approximately, up to 1.2 billion doses, assuming 100 microgram dose. We have decided and that's profit to buy additional capital equipment, hire more people, and order more raw materials to add 200 million doses per year capacity by 2022. So if you assume the 100 microgram dose, we will have 1.4 billion dose of capacity for fiscal 2022. In our words, we will build the manufacturing capacity to make up to 140 kilogram, yes kilogram, of formulated MRNA in 2022.

Now let's talk about output in above doses. Two factors that determine output, the dose for the boost and the product mix. Given the COVID-19 vaccine, previously we felt that the MRNA-1273 is currently authorized for 100 microgram dose. So if you assume the boost the MRNA-1273.351, the South African variant candidate needs 50 micrograms a dose. On the bottom left of the slide, you see a scenario in which 100% of the output is of COVID-19 vaccine authorized and we get 1.4 billion dose of 100 microgram. On the bottom in the middle, you see a scenario where we say 1 billion COVID-19 vaccine authorized vaccine, and 0.8 billion doses for boost at 50 microgram for total of 1.8 billion doses and on the bottom, right you see remarks in the worst scenario on the right.

The way to think about upward will depend on the dose of the boost and the product mix. We will learn in the next few months in the clinic about the necessary dose to get the high neutralizing antibody titer for our boost. Only one needs to think about our manufacturing capacity in some of mass. Given the flexibility of MRNA, we can in the same room and we have a semi equipment make COVID-19 vaccine and one boost and two boost and three boost, you get the point. We can run manufacturing campaign,

based on the market demand with the same manufacturing capacity, this lacks more molecule drug substance.

So with MRNA, we not only have we had speed, but we also have you had one page of manufacturing flexibility, and we are best in class efficacy. I believe this will prove crucial from a competitive standpoint for the years ahead where nobody knows what the demand mix will have to be, is a new and still unstable virus, nobody knows if one variant is going to be necessary and are enough to boost or more in the years to come until this virus is under full control.

So stick to market and flexibility of product mix and scale will be critical. We have all three, few companies do, and we also we have the partners, we don't have to get the land with somebody else with different goals, different financial incentives, different corporate decision-making process, different culture. We have moved fast, and we will continue to move fast.

On slide 21, in 2021, we are continuing to scale our commercial network. We plan to append Commission subsidiaries this year in Japan, South Korea, and Australia. I look forward to pLenti and Moderna flagging Tokyo, Isreal, and Sydney. We also want to continue to work with regional distributors. We are in advanced discussion (inaudible) Eastern Europe. With this addition in 2021, we will have a strong commercial network across the world in most critical markets by the end of this year.

On the next slide, we got united to announce earlier this year that Corinne Le Goff has joined Modern's First Chief Commercial Officer. Corinne's experience in global commercial leadership, as an executive at Amgen but also critical experience as Country Manager at Roche and her experience with digital marketing will prove invaluable.

I have had the chance to spend a lot of time with Corinne since she joined, and I'm confidence you will be more than a commercial organization, highly levered with digital solutions both externally and internally. We both share the view that there are many ways to run commercial operation in a much more modern way than traditional sales force of large pharmaceutical companies. In commercial tool, more than that will disrupt and innovate and implement best practices from many industries and be the digital commercial organization. Corinne will have a chance to share some of our thoughts and put it to you at all vaccine day on the pre-thoughts here.

This morning, we also announced that Tal, our Chief Medical Officer, we will be leaving the company in late September after 6 years of service. Tal joined us when we were a preclinical company and now we have of course the price problem. I am very thankful for Tal for taking a chance almost 6 years ago. It was not (inaudible) time, trust me that's we're going to make it, but given his deep scientific understanding and curiosity, like Stephen Hogan and I, and many of us on the team, he saw that these technology could change medicine if we could make it work safely in human. Tal, thank you so much for things you have done, it has been a pleasure of building Moderna with you on the team. I look forward to continuing working with you in the coming quarters.

The company as (inaudible) recruit a new Chief Medical Officer with global and commercial experience as the company scales up to launch the COVID-19 vaccine of course around the world. There's a (inaudible) for potential COVID boost and prepares to file several biological licenses over the next few years.

With this, now let me turn to Stephen to talk about SARS-CoV 2 variance, Stephen?

Stephen Hoge {BIO 17925815 <GO>}

Thank you Stephan, and good morning everyone. Today I want to take you through our current thinking on variant and our strategy to address them. I'll then turn it over to Tal, to provide an update on our pipeline. Let me start with a quick overview of our strategy for SARS-CoV 2 variance of concern. Last week, we published a letter in The New England Journal of Medicine with data that confirmed the Moderna COVID-19 vaccine, MRNA-1273, provides a neutralizing activity against all variants of concern tested to-date.

Nonetheless, as recent reports of increased transmission and potential re-infections of the new variants of emerge, out of an abundance of caution, we have announced multiple strategies to try to increase protection against those variants. As has been widely reported, the immune response generated by our original strains appears to be relatively weaker against the B1351 variant if or when immunity wanes in the future, this might lead to a gap in protection. We plan to close this potential gap with an update to our vaccine based on the new strains.

We anticipate different approaches for 2 distinct populations. For those who have been immunized or infected by the original strains, we anticipate boosting with a variant specific booster vaccine either alone or in combination with our vaccine against the ancestral strength. For those who are still naive to SARS-CoV-2 because they have not been previously infected or vaccinated, we anticipate updating our vaccine to provide immunity to both the ancestral strains and the new variants of concern.

Now on slide 25, you can see the clinical trials that are ongoing or planned for our COVID-19 vaccines. For MRNA-1273, the team COVE Phase II-III study in adolescence, ages 12 to 17 years, is ongoing and recently completed enrollment. The kid COVE study Phase II in pediatric populations ages 6 months to 11 years will begin in the near term. And our Phase I-II study in Japan is ongoing, led by our partner Takeda. For the various studies, we plan to test a variant specific booster candidate MRNA-1273.351 based on the B1351 variant first identified in the Republic of South Africa at the 50 microgram dose level and lower.

In addition, we plan to test a multivalent booster candidate. MRNA-1273.211 that combines MRNA-1273 and MRNA-1273.351 in a single vaccine, again at the 50 microgram dose level and lower. We are also evaluating a 3rd dose of our authorized Moderna COVID-19 vaccine MRNA-1273 at a 50 microgram dose level, which is already underway. Finally, we are planning to test a next generation vaccine, MRNA-1283 that encodes for the receptor binding domain and end terminal domain of the spike proteins and is being developed

as a potential refrigerator stable MRNA vaccine that could facilitate easier distribution and administration a wider range of settings including potentially developing countries.

And we believe messenger RNA is best positioned to address the potential threat of SARS-CoV-2 variants given several key characteristics, including high vaccine efficacy, speed and agility to make updates, the ease with which we can do combinations, and our manufacturing flexibility and scalability. I'm happy to say that we have already manufactured the first GMP batch of our variant booster candidate MRNA-1273.351, and a shift clinical trial material to the NIH for clinical testing.

Now, I'll hand it over to Tal, who will walk you through the rest of our portfolio across vaccines and therapeutics, Tal.

Tal Zaks {BIO 19987702 <GO>}

Thank you, Stephen. So, let me briefly summarize where we are in the rest of our pipeline, we have 4 other vaccine programs that are in clinical trials, the CMV vaccine is on track to start the pivotal Phase III this year. The Zika vaccine is preparing for a Phase II trial that is also expected to begin in this year and our HMPV/PIV3 vaccine is currently enrolling in toddlers. Our RSV vaccine is being studied in 2 separate trials, one in children and 1 in adults. The pediatric trial is enrolling quickly and the first 3 cohorts in the age deescalation study have now been fully enrolled.

We announced last month that we were taking our RSV vaccine into the adult population, and I'm happy to share that the first participant has since then been dosed in that trial. Just last month we announced 3 new development programs in infectious disease vaccines. Our influenza vaccine program will evaluate 3 candidates comprising multiple antigen combinations against the four seasonal viruses recommended by the WHO eventually moving one candidate into a Phase III trial.

Our HIV Vaccine program has two approaches MRNA-1644 is a collaboration with IAVI and Bill & Melinda Gates Foundation. It's a novel approach to an HIV vaccine strategy that's designed to elicit broadly neutralizing HIV-1 one antibodies. MRNA-1574 is a collaboration with the NIH, and this includes multiple native like trimmer antigens. And finally for those unfamiliar with the Nipah virus, this is a zoonotic virus transmitted to humans from animals that is either transmitted in food or through direct human-to-human transmission. It is included in the WHO R&D blueprint list of epidemic threats needed for urgent R&D action.

MRNA-1215 is a collaboration with the NIH to develop the Nipah vaccine. We also have 7 clinical proof of concept trials ongoing in our exploratory modalities, the Phase II program in VEGF partnered with AstraZeneca is ongoing. The personalized cancer vaccine Phase II, which is in combination with KEYTRUDA compared to KEYTRUDA alone that is partnered with Merck continues and the Phase I of that program in multiple cohorts is ongoing, including the upsize head and neck cohort that is currently recruiting additional patients.

The KRAS Phase I that is partnered with Merck continues. And in the intra-tumoral oncology, we have a Phase II ongoing with OX40L ligand program in ovarian cancer patients. The Phase I dose escalation for the triplet program is ongoing both as monotherapy and in combination with development and high yield 12 partnered with AstraZeneca continues in the Phase I trial.

Finally within the systemic intracellular therapeutics, the Phase 1-2 sites for our PA program are being initiated, and we plan to enter the clinic this year. This final slide has our full pipeline. And with that, let me hand it back to Stephane.

Stephane Bancel {BIO 15174250 <GO>}

Thank you, Tal. On slide 32, we have a set of care priorities for 2021 and everybody at Moderna had a chance to review them and to discuss them. Priority #1, to maximize the impact of COVID-19 vaccine, the output in 2021, in terms of number of those that we can ship to countries, the manufacturing scale-up preparing for 2022 supply, clinical development of variants and boost, and a full commitment to bring variants of concern to the clinic.

Priority #2, accelerate vaccine development and continue to bring more innovation from research lab to clinical developments, pricing of the free, generate proof of concept in therapeutics based on the success of our ability to repeat those in human of therapeutics technology with chikungunya antibodies, but also with intratumoral, we expect key data in cardiology, oncology, rare genetic disease, and then entering the clinic of our first autoimmune programs.

Priority #4, we want to continue the expansion of MRNA technology. Our appetite to invest in science and process development has not weakened, just the opposite. We believe we got at the beginning of the S curve of this exciting new disruptive technology. On slide 23, as I said earlier, this is an important inflection year for the company. Now that we know that MRNA vaccine can be approved, and we have positive cash flow, we have the ability to invest, it was like we've never had in our history. If you look at slide 34, you see some of the key attribute that energized me. M&As and information molecule, Moderna as a unique platform, we have a very strong cash position, we have very large amount of APA's, we believe Moderna will be cash flow positive this year, we believe Moderna will be profitable in 2021, the team has done a remarkable job, and I'm so proud of this team, we have a fully integrated manufacturing plant in Massachusetts and the network of partners we have (inaudible).

We have already made one of hundred million doses of drug substance of COVID-19 vaccine. We have shipped at least 60 million doses globally, and the team reviewed, we have 24 exciting first-in-class or best in class development programs that we are pushing towards the clinic -- towards the pool.

As our historic investors know, since I joined Moderna as employee #2 in 2011, we have always focused on how do we grow 10X from where we are. We ask this question to ourselves regularly. I have to admit that in 2020, I did not focus on it as intensely as in the

previous years. We are focused on moving MRNA-1273 to to Phase 1, Phase 2, Phase 3. We got authorization and on building manufacturing to deliver up to one billion dose in 2021. We did not spend much time asking how do we go 10X. We were focused on how do we get this important vaccine to finish line and get to one billion dose to the people around the world.

In early December while our team was focused on preparing for FDA VRBPAC meeting on December 17, I was starting to step back and gave reward and some of our executive team members, and asked all of them. Now that we know MRNA vaccine can get approved but we are generating cash. How do we 10X from here. The last 2 months have been already fund between event that 10X Moderna. The team is highly energized by it and so am I. We have the opportunity to become one of the most impactful biopharmaceutical company over the next 10-20 years in the world. The potential to maximize that impact on patients is what motivates us.

The team and I look forward to welcoming you to all our regular investor event. We would also vaccine them on April 14, we will also have annual science day on May 27, and we will have our annual R&D day on September the 9th. More than ever, we have an unique opportunity to have a very large impact on so many lives. This is humbling to all of us and also highly motivating to always challenge ourselves to be the best of Moderna that we can. I would like to thank our Moderna team, our partners, our many suppliers around the world, our clinical investigators, our participants in our clinical studies. I would also like to thank our investors for your trust as we embark in this new version of Moderna. The team and I will now be happy to take your question. Operator?

Questions And Answers

Operator

(Operator Instructions) Your first question comes from the line of Matthew Harrison with Morgan Stanley.

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Good morning, thanks for all the information this morning. I guess first question, can you discuss the dosing strategy around boosting and in particular, I think I understand why you're going to start with 50 micrograms. But what do you think about the probability of using a lower dose there?

And then just secondly, as far as I understand, I think that the number of doses that have been signed via APA or higher, and then the 700 million that you've talked about in terms of manufacturing supply. Can you just talk about what your thoughts are on being able to deliver those additional doses this year? Thanks.

A - David Meline {BIO 6397419 <GO>}

Thanks, Matt. I guess it sounds like. Okay, Go ahead, Stephen.

A - Stephen Hoge {BIO 17925815 <GO>}

I'll take the. I'll try to take the first one and then hand it over to Tal as well. And then, and then I think David loves to take the second. So first on 50 microgram, I'd remind you of a couple of things. So in this case is a third dose of a booster. And so I think we're quite optimistic that a substantially lower dose is necessary because the immune system has already been primed and boosted once. And this is just maturing and updating that immune response to a new variant.

And I'll note that we have, we've shared our Phase 2 data which does show that we see, at 50 micrograms even in a primary series really good neutralizing antibodies and so I think we're quite optimistic that 50 micrograms or lower will suffice as the third dose booster.

A - Tal Zaks {BIO 19987702 <GO>}

This is Tal. The only thing I'd add is that has scientific precedents, there's been data. I mean we really malaria vaccine that was published a while ago that showed that if you come in months later, you can come in with a much lower dose and that is sufficient to provide a boost. So in the context of wanting to maximize the ability to provide a benefit from whatever given capacity, I think that strategy makes sense. On top of which as Stephen alluded to, it could be that even 50 micrograms as a timing series could suffice, recall that our dose at 100 supersedes what you see with natural infection in terms of neutralizing antibodies to begin with.

A - David Meline {BIO 6397419 <GO>}

Okay thanks Tal and Stephen. On the second question, Matthew, as you know, we have been cautious about talking about supply for the year, and we have raised the number as we have understood better the learning curve of a process as we've had lots made and being able to see at the demonstrate their output. I think it's important to always appreciate this is a new tech we have never made and nobody in the world has made them on at that scale so fast, and so it's important for people to understand, we invested and based the manufacturing capacity, the ability to make a 1 billion dose, that is, having worked myself in manufacturing at commercial scale and of course (inaudible) runs manufacturing -- used to manufacturing for Novartis worldwide. There are so many unknowns at this stage that as we learn more, we are upgrading on them bills. As you know last year, early in the process, we said, we feel comfortable we get at least $500 million out of the $1 billion of infrastructure capacity. Then we were at 600. What we have seen out of the US supply chain, as you know, Europe is around 3 months behind the US because of when we started building it, we did not have no sites in Europe as as you know, we feel good about what's happening in the US, the team is doing really a remarkable job and so we feel comfortable to date to up what we could all base case, we feel very comfortable that we will deliver 700 million doses. The team is working extremely hard to get to a billion dose. They know that the every extra dose we can get out of Moderna supply chain will be used and will help protect people. So you have a full commitment to do everything we can to get us closer to a billion with that this stage what we are saying is we feel very comfortable we can deliver 700 million base plan, and we are still working to be upside, and I will not bet against the Moderna team to be able to do better. But at this stage 700 million is the base for us.

Q - Matthew Harrison {BIO 17603148 <GO>}

Okay, thank you.

Operator

Your next question comes from the line of Ted Tenthoff of Piper Sandler.

Q - Ted Tenthoff {BIO 1880164 <GO>}

Great, thank you very much. And just incredible progress over the course of the year. And David, thanks for all the clarity on the quarterly update, I'm wondering, with respect to the 200 million that was booked in the fourth quarter, what is the number of vaccines that is ascribed to that. And then if I may, will we be getting any data from the Triplet Oncology IO program this year? Thank you, guys.

A - David Meline {BIO 6397419 <GO>}

Yeah, so the $200 million of revenue was associated with the deliveries that we made to the government in the 4th quarter in the US, which was around $17 million.

Q - Ted Tenthoff {BIO 1880164 <GO>}

Thank you.

A - Tal Zaks {BIO 19987702 <GO>}

And Ted. This is, Tal, as it relates to the triplet. I hope so, you know, they data on oncology is a function of when we see responses. And so once we see them and we confirm them, then of course that becomes material information that we share, so it's hard to predict, but I would hope so.

Q - Ted Tenthoff {BIO 1880164 <GO>}

Great. And Tal wishing you all the best. Thanks for all the hard work.

A - Tal Zaks {BIO 19987702 <GO>}

Thank you. Ted.

Operator

Your next question comes from the line of Salveen Richter with Goldman Sachs.

Q - Salveen Richter {BIO 15151450 <GO>}

Good morning. And Tal, I want to second that. Good luck with the path ahead and you will be missed here. So with regard to variants, which is the 3 approaches for COVID on the 4, do you think will be optimal here and do you have updated thoughts on the correlate of protection or trial design. And then separately, should we expect your pricing

strategy for 2022 to be in line with 2021. I mean, you did mention option. So I'm just curious how we should think about that.

A - Stephen Hoge {BIO 17925815 <GO>}

Thank you. Salveen. I'll try and take the first part of that, those questions. So as far as what optimal. I think we have to run the clinical experiment to know and that's why you see us taking the 3 approaches. It is entirely possible maybe even desirable that 1273 as a 3rd dose is able to boost immunity above a level that would be necessary to provide long-term protection against the new strains. But if you look forward and say at some point in the future, we're going to be perhaps in a regular boosting environment, what would be the ideal vaccine it seems logical that vaccine that provides the broadest immunity, so not just against ancestral strains or a boost against the new strains would perhaps do the best mode and that's where I think the blended approach, so 1273.211 as we announced today might ultimately be the right long-term product, but in the near term, we got to run the clinical experiments to get the answer.

A - David Meline {BIO 6397419 <GO>}

Thanks, Stephen. And on the pricing question's Salveen at this stage, we have not disclosed any information on pricing. The piece that I can share as this all these, as you know, we have a high efficacy vaccine, governments understand the ability that we have to move fast on variants, and of course, they care deeply about that ability that use of our technologies and other companies. And so in due course, as the 2021 year progresses, we'll be sharing more color on the pricing strategy for 2022, rainfall, both of the prime series as well as the variant. It might be the same, it might not be the same. So we will discuss that in due course. Thank you.

A - Tal Zaks {BIO 19987702 <GO>}

And Salveen, this is Tal. Thanks for your kind note, and I wanted to answer your question about the correlate. I think the work continues, its being primarily led by NIH who have access to all our samples, as well as the other BARDA funded trials. The current assumption is that we should be able to move even without a correlate and that is consistent with the recent FDA guidance on the development of a variant vaccine.

I think if there does emerge a correlate of protection, we will make everybody's life easier, especially those coming up in our footsteps in terms of licensing new vaccines. But I think also for us, the ability to peg the dose level will be substantially made easier with it. So we continue to work towards that goal. We'll see in the coming months with the one emerges.

Operator

Thank you. Your next question comes from the line of Michael Yee with Jefferies.

Q - Michael Yee {BIO 15077976 <GO>}

Hi thanks good morning and again congrats on all the progress. Two questions, one is a variant timing manufacturing question and one is a competitor question. I guess based on

what you described today, can you just kind of walk through the timing of how to develop and what would be needed to get a variant vaccine approved and when you would be able to flip the switch to start making that answers your question one for variant.

And then related to that, maybe for Tal before we let you go, maybe you could comment about how you think about variant vaccine for MRNA versus adeno, particular with multiple strains in there, how do you think about comparing and contrasting. Thank you.

A - Stephen Hoge {BIO 17925815 <GO>}

So maybe I'll take the first part of it and then hand over to Tal for the second. I think, so first on how quickly we think this goes. We've already I think demonstrated that we can pretty quickly produce a new batch and if you look back when we announced that we started manufacturing may even faster than last year, we do think the clinical program for testing of this is pretty straightforward based on the recent FDA guidance and other public comments, it's likely to be in the hundreds of people and immunogenicity and safety as important endpoints there, but ultimately, that will be subject to discussions with the FDA.

And so we think we could get to clinical data here relatively quickly, they'll be able to demonstrate the potential for a booster vaccine to close a potential gap in immunity.

As far as production, that will depend a lot on the demand picture and possibly that data. But as Stephane noted, our manufacturing system is really, we believe, we could almost copy and paste the new information into those manufacturing systems and proceed very quickly to be updating our vaccine or produce booster. Tal, do you want to take the second part of that?

A - Tal Zaks {BIO 19987702 <GO>}

Yeah, that's, that's a softball. Look the MRNA, the beauty of the MRNA technology is the fact that the immune system doesn't recognize the LNP per se. It only recognize is a protein that we keep somebody to make. And so I believe that our vaccine platform is optimally suited to boost irrespective of what primary series somebody got whether it was a protein in MRNA or frankly an adenovector.

I think the challenge with the adenovectors for both the initial boost and certainly any work with variants down the road is going to be that the adenovectors generate significant immunity against the other components of the adenovirus and thus have the risk of limiting the ability to translate the transgene and therefore, if you look at the boosting delta that is how much additional antibody levels do you get from a boost. With adenovector, you can get a boost, but the magnitude of that boost is invariably less, the magnitude of the boost to get with an MRNA platform and that is true just in the first boost. I suspect that if you needed to come with a 3rd dose or a 4th dose or variant specific vaccines, it would be challenging to get the requisite amount of specific immune recognition towards the new transitory gene.

Q - Michael Yee {BIO 15077976 <GO>}

Yeah. Thank you.

Operator

Your next question comes from the line of Gena Wang with Barclays.

Q - Gena Wang {BIO 18848097 <GO>}

Thank you for taking my questions. Tal, good luck with your next journey. It's a big shoes to fit and you will certainly be missed here. I have 2 questions regarding the variants and also next generation COVID vaccine 1283. So for 1283, is it shorter sequence that make storage feasible. And also with the sequence outside of RBM sequence, is a RB motif sequence.

And then the second part of question, the CoV-2 variant, for the NIH study. I was wondering if you can give a little bit more color regarding type of subjects you have enrolled, whether it's a vaccine or experienced subject and also the booster time.

A - Stephen Hoge {BIO 17925815 <GO>}

Thank you for the questions Gena. I'll take the first part of that and then hand it over to Tal, to answer the NIH component. So in terms of the MRNA-1283. It is correct. It is the fact that it is a shorter MRNA does help with the long-term stability and does facilitate, we think moving that into a refrigerated vaccine. It's not the only feature. And as you know we've had advantages in our MRNA platform based on our long history of working in it for instance that we are functioning right now already, as it has been noted in our normal freezer for up to 6 months and actually already doing 30 days with MRNA-1273 in a refrigerator.

And so it's, it's a benefit. But we're already well in that path, even just with 1273. I think the second part of your question was, is it just the RBM and 1283 covers both the RBD and the end-terminal domain. And as it has been widely reported, those are particularly important for neutralizing activity in immune system against SARS-CoV-2 virus.

A - Tal Zaks {BIO 19987702 <GO>}

Thanks, Stephen. Hi, Gena, thank you for your kind comments. The NIH, I'll defer to my colleagues there to describe their trial in the coming weeks once we launch it. But in essence, the answer is both. They will have Orange there that we'll be testing the new variant vaccine as a boost in those who have been previously immunized on their Phase 1 trial and then there will be a component that will test the new vaccine in the primary series.

Q - Gena Wang {BIO 18848097 <GO>}

Okay. Okay, thank you.

Operator

Your next question comes from the line of Cory Kasimov with JPMorgan.

Q - Cory Kasimov {BIO 3009346 <GO>}

Hey, good morning guys. Thanks for days for taking the question. All the detail today and all the best to Tal. Although it's good to know, we will have you for a couple of more quarters. So 2 questions from me as well. Look I realize, it is not much you can say on pricing beyond 2021. But as we think about your booster strategies that could be less frequent at lower doses as well as the greater supply of vaccines we should have on the market balanced against the potential waning the pandemic.

Are there scenarios where the price per dose could be either materially higher or lower than what we're looking at in 2021. And then my second question is, from a modeling standpoint, should we be assuming anything in the model above and beyond what was talked about today, that could be owed to the US government for the initial co-development of your COVID vaccine or is that what David was referring to with the royalties that are included as part of your cost to sales. And if so, should we just be assuming a generally stable rate going forward, or those change at all.

A - Stephane Bancel {BIO 15174250 <GO>}

So there's a lot to impact. Let me start maybe on pricing. So it's quite interesting, because as you know, this is public information. There are some vaccines that have been made available to governments at free developed dose and as you know we walked you through our pricing strategy back I think in August on the Q2 call. Then, one of vaccine is price much higher and I think it goes on to a few things. And the most important one is efficacy, governments care about saving lives. Governments care about getting their countries back on their feet. And so what we are hearing from governments, literally almost on a daily basis as we engage with our existing government contacts, there is some new ones that are occurring us, is there starts to be a very clear differentiations between the different products that are either available already or that they're getting very close to authorization, and I wish if I had the crystal ball last year that we would have built more manufacturing capacity for 2021, but I did not anticipate nor I think anybody did that there'll be such difference of efficacy between vaccine, that the MRNA vaccine will be such high performance, as you know, some countries decided to invest in us to procure the vaccine in adeno or protein technology, because we were better understood and as we know what happened in 2020, in some of the clinical data, that has played a big also, it's quite interesting that -- to see how people are reacting in the countries. If you follow the media, for example in Europe, where several vaccines have been authorized. As you know in US, we have as of today, (inaudible) meeting tomorrow, but only 2 MRNA vaccines authorized in the US, but if you look at what is happening in some countries in Europe, as well as what is happening in different countries around the world, I think governments because of the scientific advisors and clinical advisors and because of what do you, the aim to reduce the pressure on the healthcare system, our hospitals. First, what is quite fascinating and I'm sure you're all observing it is that and at least is the first time in my career being 20 years in this business that in the media, every day you hear about vaccines on TV, in the newspaper, online, and you have the product efficacy that's is all over the news every day. This is going to happen to my knowledge, for any of our product. And so, yeah, it is very interesting for them is happening, so since you have the clinicians, MLCs, the pharmacists, but the consumer too. That's believing that those

products are not all the same. And this I think will be a very important differentiation as we move into 2022. as we move more to a traditional commercial markets where it's not governments buying directly, but the traditional kind of a retail channel and the impact, I think of a consumer's desire to ask our product when he or she walks into a pharmacy or the GP's office, will be quite significantly different from what we have used to develop our products.

A - Tal Zaks {BIO 19987702 <GO>}

Maybe then I would comment on the question about cost of sales. So you know, Cory, what I did try to say early on was that, we don't have precision in all cases, in the case of cost of sales. I would say there are puts and takes that we're monitoring, but we gave you the 20% percent because we feel confident that that's the right range right zone that we're in. And yeah, as we move through time, there's going to be more information as we ramp up our factory capabilities and answer some of the other questions, but I think you're good for now with that modeling assumption.

Q - Cory Kasimov {BIO 3009346 <GO>}

Okay, great, thank you guys.

Operator

Your next question comes from the line of Geoff Meacham with Bank of America.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey guys, good morning and thanks for the question. And also wanted to offer up best wishes to Tal. A question on manufacturing investments, I guess for Stephane. So I get the focus on variants with the booster and clearly you guys have to fund many assets progressing the pipeline, but how flexible are your manufacturing investments, I guess the question is as the case as a globally continued to decline, is there a way to scale back some of that capacity should, should lower volumes become the norm. Thank you.

A - Stephane Bancel {BIO 15174250 <GO>}

Yes, good morning. Those are great questions. So in term of the flexibility, as I described in my remarks. The only raw material that is different from MRNA-1273 to MRNA-1273.351 is only of the plasmids, the enzymes are the same, the repeat is the same, in the same equipment, in the same rooms, with the same people. So the flexibility of this technology is really incredible for people that have worked, we were confident that like I used to do at Lilly and as you know, I have trained as a biochemical engineer doing the TruSeal and E coli production in bioreactors. It is -- it is literally (inaudible) we use disposable reactors, you get new consumable plastic bags soon as your reactors and here you go again, you just need to change that could different plasmid because we use disposable reactors and not stainless steel, you don't have to spending a lot of things cleaning validation because we basically dispose of things. And so the flexibility is quite incredible, you just need a new plasmid. And so because of so it's not very expensive part of the cost of the total cost of the finished product that is filled in the vial because you have to make the MRNA, you have to formulate it, and then you will have to fill it in the vial.

Ordering a lot of plasmid at risk for the variant, is a great opportunity for the company. We are very, very held on payment, so that's a piece that I think make this technology very unique on the ability to scale and the ability to be flexible to respond to different demand, is there where we potentially might end up with a different combination of mutant boost down the road in different continents, maybe, I don't know.

Again, it would be market-driven, but if it is what the market requires, we can accommodate that in a way that is totally atypical to what the industry could do at the speed, which was so I think will surprise many because again we make this order puts in the same reactors. In term of taking down the manufacturing capacity, if we don't need let's say in 2023 or 2024 this same amount of volume because of a massive boosting as we say, it's actually interesting because as you know, we have, we know with plans, we have have quite a lot of capacity, but also we have some capacity in Lonza, in New Hampshire, and also capacity in Switzerland where they have several lines of manufacturing. So we are actually quite a lot of flexibility to take capacity down at Lonza, either in the US and/or in Europe, at different time points.

So that's one point, the other piece we should not forget is the pipeline, and I will just make 2 comments, which I think are very important. It's one of the same. Why. Actually I was building manufacturing to that scale is is going to be so enabling, so more than that to keep growing and growing and growing. First is the other vaccines, CMV is ready to move into Phase 3 as we said, this year. We will give you updates on the true program, but I will remind everybody that there is in the Caribbean end points. We've a regulator for seasonal flu vaccine. And so we anticipate that the development of the flu program will be pretty quick. And as we discussed on previous call, one of, what kind of optimal target product profile for down the road, will be a product that is both seasonal flu waiver, the current spring of flu. But we saw a boost for COVID-19 with a relevant strength at that time in the same dose.

So we anticipate, we should have high efficacy for flu as much as for the MRNA virus which is a (technical difficulty) virus, like the SARS-CoV-2. And so that is where we are going. We've more vaccines coming to the market. And then there's also always therapeutic pipeline and the piece, I think that's actually quite good for us. That we something vaccine the scale up. If I go back to, which is if you think about some of our product, as you know 1273 requires 100 microgram per human per dose, but if you look at the chikungunya antibody program that's used the no NVIV formulated MRNA that we use or so in the rare disease program for example what we showed it is very good data at 0.1 mg/kg, so in a 70 kilo adult, it is 7 milligram compared to 100 microgram. So as we move the therapeutic pipeline fell very into development, but the proceed to commercial, we're going to need much more mass of a mining. And so I actually I'm spending a lot of time thinking we are one, how do we keep adding capacity to manage the entire pipeline that this progressing.

We have a flexibility, we have loans and that's why we did this, where we, one, so we are used to take turns down if we need to, but if I was a betting man how we bet review that we're going to be more adding, prevent thinking capacity down, because of the probability of technical success as I've said all along, I believe we will launch the CMV vaccine given the data we have, the medical need and the biology, you were able to do

with both depends on the end GB and so as opposed to anytime we want to think about how do we do more.

Q - Geoff Meacham {BIO 21252662 <GO>}

Okay. Thank you, Stephane.

Operator

Your next question comes from the line of Hartaj Singh with Oppenheimer & Co.

Q - Hartaj Singh {BIO 18796450 <GO>}

Great, thank you for the question. And Tal, I wish you the very best in your future endeavors. Thank you. The question I have is, we're hearing more and more about some constraints in the raw materials that go into making vaccines, plasmid MRNA, things as simple as pipettes, et cetera. Can you just give us some color and visibility on where Moderna's with its partners Lonza and others in this regard to 2021 and 2022, Stephane. And then could that be a rate-limiting step as you think about other modalities. Thank you for the question.

A - Stephane Bancel {BIO 15174250 <GO>}

Thanks. So as we've said all along, which is why we gave a range and one number up for expected supply in the year. I think one number is a very dangerous strategy, as we said know those type of consumable are of course important you know we are in a regulated business and we cannot start to make a product until we have all the components, all the raw materials, the entire trained team, and so on and so forth.

We have a lot of interaction and our plan is to check a lot of things before you can start the engine, wherein in GMP manufacturing, we have to do the same to ensure the quality and the safety of the product. And so what I think the team has done a very good job last year, if as you recall, we started racing against this virus in very early January and it's in the late January time frame that we started to say this could turn into a pandemic.

And we started to think bigger and so one at a team and I spent quite a lot of them as we are starting to think about. Okay. How do we go if we had to make a billion dose in 2021, how do we do that. I used to run the supply chain that Lilly globally, and we went right way to talk to our suppliers and one of the thing we had to do and if you recall, we did an important capital raise in May of last year, which was very important for getting us to where we are today is some suppliers because the increase of mass of product we're ordering from them so gigantic, you know that 1,000 times more and the 2,000 times more than the year before.

As you can imagine, many of them looked at it was a bit funny, and we are very worried, they were worried that if the drug would fail, there might be in trouble because there we have to get these type of increase of capacity to sometime buy new equipments, hire more people, buy their own raw materials to make all raw materials for our product, if that makes sense. And so, sometimes what we have to do with the team is actually to pay

upfront the entire purchase of product so that, there we go and take that cash and start to invest to quick scallop. So we took a lot of business risk last year that we thought were necessary to ensure we could deliver this year on the outputs from the manufacturing supply chain.

So I think we're in a good place. Do we have enough from time to time in the one component that given us a sleepless night because it's very tight. It's happening because the ramp-up, the industry is doing is unprecedented. But so far so good. And we are extremely on top of it. Including as we do things like increasing capacity that we announced last night to right away not only buy new machine, but right way place new orders for raw materials and make sure we keep increasing our safety stock, so that we run this more and more as a regular business where you have 50 stock on site.

So if your supplier ask a bump in the road, no attempt breaking or something else that we are able to manage that variability, which is normally manufacturing without impacting our ability to maximize our own output.

Q - Hartaj Singh {BIO 18796450 <GO>}

Great, thank you, Stephane.

Operator

Your next question comes from the line of Simon Baker with Redburn.

Q - Simon Baker {BIO 2415399 <GO>}

Thank you for taking my questions. 2 if I may please. And firstly, just going back to cost of goods sold you hopefully given us the 20% figure for 2021 but presumably, there will be some degree of variation through quarters. So would it be fair to assume that you will be exiting the year at a figure lower than 20%, and I just wonder if you could give us some color on, if that would be meaningful utilized 20% and then moving away from COVID to CMV, you've said that the peak sales potential for the CMV vaccine could be around $2 billion to $5 billion per year, it would seem that HPV is a pretty good roadmap for the potential in that space and set against that $2 billion to $5 billion looks quite conservative.

So I was just wondering if I'm missing something in that analogy or whether that $2 billion to $5 billion is out of an abundance of caution. Thanks so much.

A - David Meline {BIO 6397419 <GO>}

Yeah, maybe I'll take the first one on the cost of goods percent of sales, our advice right now is to assume that's pretty stable through the year including as we exit the year, so I would, I would recommend you model it consistently. There will be some ups and downs, and the ups and downs are more related to the mix of business and the price levels of the product, that necessarily changes in the cost of the produced product and hence given that, we get out towards the year-end. We don't have complete visibility on precisely what the book of business and mix will look like of sales. Hence some uncertainty around the the precise percentage number, but again I would advise just treating it as a constant for

now. And then as we get better information, we'll give that to you as we move through the year.

A - Stephane Bancel {BIO 15174250 <GO>}

Thank you, David. So let me take the CMV question. So a few bit of calls on the $2 billion to $5 billion and you have a peak sales estimate that we talked about, now available. You know, we talked about that as a company that never had run the Phase III at the time, that has never launched the product or get the products approved at the time, but that's zero commercial employee at the time. So we did the analysis outside commercial costs within company and with our Strategy team and the team here that many of us have commercial experience, so we tend to be cautious because as a new company, we want to make sure that we build credibility and the credibility in life has to be earned.

And so I will just make the analogy to manufacture in the sense, we built the big-enough capacity and we are very upfront to the financial community about it last year when we did so. But we said, look, given the unknown on raw material supply, given the unknown on yield, we feel comfortable we could get at least 500 million dose out and then as we will learn more we move to 600 and as we learn more, we move to 700 million, so do I believe it is possible that we are going to sell more than 5 billion dose of CMV, yes, I believe it's possible because it's an incredible unmet medical need. As the world develops, I think the piece you want us to be careful about peak sales is peak sales when, peak sales slightly after launch or peak sales 25 years after launch because any of those vaccines (technical difficulty) that product, there is of course inflation, there is of course the developing countries that are becoming richer and richer. So is there upside to the number, I believe there is upside to the number, but that's all I am gong to do right now as a company.

Q - Simon Baker {BIO 2415399 <GO>}

That's very helpful. Thank you.

Operator

Your next question comes from the line of Manny for higher with SV8 Leerink.

Q - Mani Foroohar {BIO 20015167 <GO>}

Hey guys, thanks for taking my question. Tal, looking forward to chatting with you later on today in our fireside chat and excited to hear at some point what your next venture is going. A quick and from a boring financial questions. I'm as we, as you guys are pretty clearly going to transition to profitability, cash flow positively on a, at least in the near term, very durable basis, when would you consider changing your current treatment of your NOL allowances how that's, how would you communicate that, how that flow through, how you communicate your financials from modeling perspective.

And then secondarily, and maybe scientifically more interestingly, how do you interpret the data suggesting that at least for the adenoviral approach from J&J, but also from your own data on the other MRNA vaccine that titers that should improve over time. And so it

nearly improves over time and the gap in risk and efficacy against the so-called South African variants. And as for Wuhan variants seems to close, that would suggest to me the 1273 should have similar efficacy versus the South Africa and the Wuhan variants.

Am I interpreting it the same way you are or am I missing something?

A - David Meline {BIO 6397419 <GO>}

Yeah. So maybe cover the first one. On the tax rate, as I said, what happens is, we're carrying this net operating loss with a full valuation reserve right now against the deferred tax asset that comes with it. So that will of course get released as we start generating pre-tax income, and it's likely based on the current book of business that we would consume during the year the entire loss carried forward. So that's point one.

Point two is from an accounting perspective, what happens is you, you basically project a full-year tax rate, including the consumption of that deferred tax asset. And then you start accounting quarter by quarter based on that average of the full-year rate. So it actually from an accounting perspective doesn't matter. The timing of the release of the NOL, the deferred tax asset and the valuation reserve. So that's why I tried to be clear with the mid-teen percentage including in Q1 because from an accounting perspective, it would be stable unless we have some other changes that cause the full-year rate to change as we move forward. Hopefully, that's clear.

Q - Mani Foroohar {BIO 20015167 <GO>}

Thanks. I misstated my question, actually met versus severe disease and mortality in terms of the similarity and efficacy along as longer-term follow-up.

A - Stephen Hoge {BIO 17925815 <GO>}

Sure. Yeah. So thank you for that question, so let me take a stab at it. I think we are, as you noted, and we had nearly essentially 100% efficacy against severe disease, 94% against mid to moderate or any disease. And I think that gives us great optimism about the current 1273 vaccine that's been authorized is protecting and even if the new strains are slightly more growth, that we'll be in good shape. I think the question though is, at some point you would expect coronavirus immunity to wane, and that's because in all of the human circulating coronavirus is that's what happens.

The durability here, has always been a question. Is it a year, is a 3 years, is a 5 years. I think as you see new strains emerge like the potentially concerning strains that we've been talking about particularly a refocus South Africa and Brazil, you have to ask the question is that, is that what does not look like, not just now, but what does that look like six months from now, a year from now, as we start to move into a mode where we're going to see seasonal epidemics of coronaviruses which we already see for the other coronaviruses and you would have to assume what will happen with SARS-CoV-2.

And it's for that, it's those gaps in immunity, that I think we're particularly focused on right now, which is to what extent do you work, to what extent in the future do at-risk populations emerge with increased risk against these new strains. It's not something you

can see in the data in the first 30, 60, 90 days post-vaccination in the current clinical trials, but it's something that you, we did talk a lot about last year, and I think is going to continue to be something we have to track closely as we look ahead.

Q - Mani Foroohar {BIO 20015167 <GO>}

That's helpful. I guess that would imply also that there won't be useful to look at sera collection from the already vaccinated patients, 108 days, et cetera further days out and perhaps perform the same, the same experiment described in The New Journal Medicine article, would you consider disclosing that data or do you think it just makes more sense to just move to your more novel variant approaches and just let the clinical data speak for itself.

A - Stephen Hoge {BIO 17925815 <GO>}

To your question, I mean, look, I think we will obviously update data on durability of responses across our Phase 1, Phase 2, Phase 3 trials as that comes out and looking forward, it's prudent and if we can, we will be providing updates as well against the new strains. I think what we're saying about the variance and strategies against it is I think none of us want to be in a situation where we wait until there are re-infections and increased morbidity and God forbidden mortality in a seasonal epidemic.

For instance, this winter in the northern hemisphere is coming winter and and then say okay now time to be boosting people. And so, as we're continuing to face an involving virus that is changing its stripes and perhaps decreasing the durability of our immunity, we're trying to be very proactive with the 3 strategies we described. And I think we will continue to follow things like the data that you pointed to, which is how are we doing in terms of immunity in lot of people previous been vaccinated or previously infected, will obviously closely be following re-infections.

And then I think we all have to be following very closely what's happening in the southern hemisphere because as they move into their winter and a potential, potential seasonal spike in the winter as you normally see in temperate climates. It will help us understand to what extent are we still in a, we have to stay ahead.

And then a concerning phase of this epidemic or a pandemic or is it a place where we start to get more and more confident that the vaccine and the virus are under control.

Q - Mani Foroohar {BIO 20015167 <GO>}

Great, that's very helpful. Thank you.

Operator

At this time, I will turn the call back over to Stephane Bancel for closing remarks.

A - Stephane Bancel {BIO 15174250 <GO>}

Thank you very much everybody for joining us. We look forward to seeing you at the next event on April 14 for vaccine day, and I wish all of you stay safe. Have a great day. Bye.

Operator

Thank you, ladies and gentlemen, that concludes today's conference call. You may now disconnect.