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EDITED TRANSCRIPT

MRNA.OQ - Q4 2020 Moderna Inc Earnings Call

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OVERVIEW:

Co. reported 2020 total revenue of $803m and net loss of $747m. 4Q20 total revenue was $571m and net loss was $272m.

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PRESENTATION

Operator

Good morning, and welcome to Moderna's Fourth Quarter 2020 Conference Call. (Operator Instructions) Please be advised 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 - *Moderna, Inc. - Senior VP & Head of IR*

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 Stéphane 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 2 of the accompanying presentation and our SEC filings for important risk factors that could cause our actual performance and results to differ materially from those expressed or implied in these forward-looking statements. We undertake no obligation to update or revise the information provided on this call as a result of new information or future results or developments.

On Slide 3, please see the important indication and 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 Stéphane.

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

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 propose to start first 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 will share our business objectives and why we are so excited for 2021 and the inflection point this year will represent in our history. Stephen will start with an update on our approach to variance of concern and then Tal will provide an update on 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 III COVE study of our COVID-19 vaccine showing efficacy around 94%. Our COVID-19 vaccine was authorized by the FDA and Canada Health in mid-December and we shipped [80 million] doses to the U.S. government and the Canadian governments by year-end. We laid the groundwork for a global organization, adding commercial subsidiaries in 8 countries, 8 countries. By year-end, we have signed $11.7 billion of advanced purchase agreement for our vaccine.

A team of a little over 1,000 members did all that. And we also continue to invest in science to improve further our mRNA platform. And we also advance on 20 programs in development across 5 therapeutic areas. And we did it without a large global pharmaceutical partner.

The Moderna team executed swiftly and superbly in carrying out the complicated Phase III study while achieving remarkable diversity. The Moderna team secured the authorization of the COVID-19 vaccine by regulators. The Moderna team built out our manufacturing capacity, scaling up across many manufacturing processes, partnered with Lonza, ROVI and Catalent, and shipped close to 80 million doses by year-end. For context, we had made less than 100,000 doses of medicine in 2019. This was roughly a 200x increase in 12 months. And we're on our way to produce as many as 1 billion doses in 2021 and more in 2022.

In 2019, we had no authorized products. We had negative cash flows from operations every quarter. And we anticipated needing multiple capital raises over at least 5 years until CMV would produce sufficient revenues for Moderna to break even in terms of cash flows and become a self-sustaining company.

In 2020, we had our first product authorized and our first product revenues in the last 2 weeks of Q4. We had 2 quarters of positive cash flows from operations. We ended the year with a strong balance sheet and with cash generation in 2 quarters.

Moderna has been changed forever. Moderna has been changed in a profound way. Moderna is now a commercial company with subsidiaries in 8 countries and a direct presence in many more through commercial distributors and partners.

mRNA is an information 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 the 12 short months of 2020. And we have a capital to invest and scale.

On Slide 6, you have a summary of the countries in which we received emergency use authorization or conditional approvals and all were -- started rolling submission that we did.

On Slide 7, you get a 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, an incredible commercial team and commercial partners. We now have commercial operations in the U.S.; in Canada; in Europe, in the 5 largest markets, Germany; France; Italy; Spain; and the U.K. We established one in Switzerland, where we have both commercial capabilities to serve the Swiss market as well as manufacturing for geographies

outside the U.S. with our partner Lonza and the support teams that we need in finance, HR, digital and legal. We have partnered with Medison in Israel 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 all our products. These markets on the slide are some of the largest markets in the world. So by building the commercial network for the launch of our COVID-19 vaccine and deciding not to partner, we have actually financed and built the commercial network for all of our programs.

We have become a fully integrated company, and in 12 months, proved that we're capable of running complex Phase III studies, scaling up manufacturing to commercial level, making hundreds of millions of doses per year and building our own 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, this is just the first product that we are launching. We have a platform, and our molecule mRNA is an information molecule. This is just the beginning.

We are going to soon start a Phase III study for vaccine against CMV, cytomegalovirus, the #1 cause of birth defect. There is no approved CMV vaccine on the market. The pharma industry has strived for around 20 years to make a vaccine against CMV. This is a complex virus, a vaccine of 6 mRNAs per dose, over which are 2 from a complex protein called pentamer. We believe that CMV vaccine will present potential annual peak sales between $2 billion and $5 billion.

We have 3 programs in Phase II of personal cancer vaccine in melanoma or OX40 ligand in ovarian cancer and injected in patients' hearts, post heart attack, to revascularize their heart with new blood vessels. We have had 12 positive Phase I results.

In addition to our COVID-19 vaccine, we have 8 infectious vaccine candidates, all for first-in-class vaccine like against CMV or what we believe could be a best-in-class vaccine like with influenza. But we also have a remarkable therapeutic pipeline. We have candidate therapeutics in immuno-oncology with 5 medicines in the clinic, 4 in rare disease program, 2 cardio program and 2 autoimmune disease programs.

If you think about it, Moderna is going after the 4 leading cause of death by disease area: infectious disease; cancer; cardiovascular disease; autoimmune disease. The total addressable market is very large. 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 lab to clinical development soon. So stay tuned for that. We announced yesterday that we are increasing our base manufacturing plant for the number of COVID-19 doses we will produce in fiscal year 2021 from 600 million to 700 million doses, given the strong start of our U.S. operation and initial ramp of our outside-the-U.S. operation. Our team is still working hard to get us up to 1 billion doses for fiscal year '21.

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

David W. Meline - *Moderna, Inc. - CFO & Principal Accounting Officer*

Okay. Thank you, Stéphane. Before reviewing the financial section of the slide deck, I want to comment on the approach we've taken sharing this information. This starts with the 3 Cs, these being clear, complete and comprehensible. Today, we are presenting our results primarily on a U.S. GAAP basis. And in 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 our 3C 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 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 through the lack of alternative use.

With this context, let me turn now to Slide #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 our 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 expensed $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, pre-launch inventory buildup and expenses associated with the equipment and lease 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 our 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 costs related to the production of inventory as well as costs for 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 or 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 of our COVID-19 vaccine.

Lastly, let me comment on certain tax-related items. The significant investments in our research and development and start-up activities to develop the mRNA platform over the last decade has resulted in a net operating loss carryforward 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 maintain a full valuation allowance against our deferred tax assets related to these loss carryforwards. 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 for 2021, starting with an overview of advanced purchase agreements for our 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 U.S. 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 of 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 for expected 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 1 billion doses for 2021. Further, we expect a range of related -- of released doses in Q1 2021 of 100 million to 125 million doses and 200 million 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 model total cost of sales as a percent of product sales to be approximately 20% 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 taxpaying status as we deliver on our COVID-19 vaccine contracts to customers. As a U.S.-based company, we start with the statutory 21% tax rate. This is impacted by global sales mix to the extent that non-U.S. rates are generally lower than in the U.S 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 our book of business evolves further.

Lastly, regarding capital investments. We currently plan 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 Stéphane.

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

Thank you, David. Let me now discuss 2021 on Slide 17. We are still in February, and the Moderna COVID-19 vaccine is now authorized in 37 countries, and our team is continuing to engage regulators in new geographies, like Japan, Taiwan, the Philippines and more. We're also well on our way in the rolling submission process to the WHO, which will be key for low-income countries access via COVAX and UNICEF if we get the partnership done.

We are committed to our principles of global access to our new class of medicines, where we recognize that the need for scale up of manufacturing operations have led to supply going to the U.S., Europe and other countries. We are working with COVAX to provide low-cost vaccines to the poorest countries and look forward to supplying our vaccines for COVAX Gavi and becoming a company that will be part of the global health infrastructure for many years to come. UNICEF is the procurement arm of COVAX.

On Slide 18. As I shared in my 2020 shareholder letter, which we posted publicly on January 4 and which you can access on our blog if you have not read it, I believe that 2021 is going to be the most important inflection year in Moderna's history. You can see the 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 in a recent town hall, I almost wished I could change the company name to help our team understand the magnitude of the change.

We used to believe that mRNA vaccine could be authorized and become commercial. We used to have negative cash flows from operations each quarter since our founding in 2010. We used to work to raise additional capital regularly and thought we needed to do that for another 5 plus years until CMV will get the company's cash flow breakeven. But we have been through an incredible pivot. This is not the same company.

Now we know that mRNA vaccine can be authorized and become commercial. Now we have 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's a drastic difference between believing in an outcome and having negative cash flow versus knowing an outcome and having positive cash flow. Our appetite and our ability to invest has been transformed. We are not the same company now that we 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 advanced purchase agreements for fiscal year 2021 deliveries. We still have multiple discussions ongoing about additional APAs for 2021. So these have not been signed yet, so they are not counted in the $18.4 billion. We'll update you each quarter about the signed APAs for fiscal year 2021 as we report sales recognized with the shipment of our COVID-19 vaccine.

We increased our manufacturing base plan for the year to 700 million doses and are working hard to get to 1 billion. We are working with COVAX and its procurement arm, UNICEF, to maximize the availability of our 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 telling us that they now see 2 classes of COVID-19 vaccine based on efficacy, and they would like more of our vaccine given its high efficacy. Second, variants. Government and political leaders around the world are concerned about the emergence of several variants. They have been very clear about it, and some of them have started to request options for 2022.

With the start of the fall season soon in the southern hemisphere, with a large population of the world and with a large population of immune-compromised patients, like HIV-positive patients, we're hearing daily that governments around the world and the COVID teams worry that boosting people with variants will be an important strategy over the next couple of years to get this virus under control.

So we decided to add manufacturing capacity. We have communicated previously that our 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 have started to buy additional capital equipment, hire more people and order more raw materials towards 200 million doses per year of capacity for 2022. So if you assume a 100-microgram dose, we will have 1.4 billion dose of capacity for fiscal year '22. In other words, we will build the manufacturing capacity to make up to 140 kilograms, yes, kilograms, of formulated mRNA in 2022.

Now let's talk about output in number of doses. Two factors determine output: the dose of a boost; and the product mix. Given our COVID-19 vaccine, previously referred as mRNA-1273, is currently authorized for 100-microgram dose. So with using the boost like mRNA-1273.351, the South African variant candidate, needs 50 microgram per dose. On the bottom left of the slide, you see a scenario in which 100% of our output is our COVID-19 vaccine authorized, and we get 1.4 billion doses at 100 microgram. On the bottom in the middle, you see a scenario where we sell 1 billion doses for COVID-19 authorized vaccine and 0.8 billion doses for boost at 50 microgram for a total of 1.8 billion doses. And on the bottom right, you see the marks and -- another scenario on the right.

The way to think about output 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 a high neutralizing antibody titer for our boost. Only, one needs to think about our manufacturing capacity in terms of mass. Given the flexibility of mRNA, we can, in the same room and with the same equipment, make COVID-19 vaccine and/or 1 boost, and/or are 2 boosts, and/or 3 boosts, you get the point. We can run manufacturing campaign based on the market demand with the same manufacturing capacity, just like small molecule drug substance.

So with mRNA, we not only have the advantage of speed, but we also have the advantage of manufacturing flexibility and we have best-in-class efficacy. I believe this will prove crucial from a competitive standpoint for the years ahead, where nobody knows where the demand mix will have to be. It's a new and still unstable virus. Nobody knows if 1 variant is going to be necessary and/or enough to boost or more in the years to come until this virus is fully under control.

So speed to market and flexibility of product mix and scale will be critical. We have all three. Few companies do. And we also, without the partners, we don't have to get aligned 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 open commercial subsidiaries this year in Japan, South Korea and Australia. I look forward to planting the Moderna flag in Tokyo, Seoul and Sydney. We also want to continue to help regional distributors. We are in advanced discussions with partners to cover ASEAN and also 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 were delighted to announce earlier this year that Corinne Le Goff has joined as Moderna's first Chief Commercial Officer. Corinne's experience in global commercial leadership, until recently at Amgen, but also her 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 confident she will build a Moderna commercial organization highly leveraged 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, too, Moderna will disrupt and innovate and implement best practices from many industries and build a digital commercial organization. Corinne will have a chance to share some her thoughts and present to you at our Vaccine Day on April 14.

This morning, we also announced that Tal, our Chief Medical Officer, 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 our first authorized product. I am very thankful for Tal for taking a chance on us

6 years ago. It was not obvious at the time, trust me, that we were going to make it. But given his deep scientific understanding and curiosity like Stephen Hoge and I and many others on the team, he saw that this technology could change medicine if we could make it work safely in humans.

Tal, thank you so much for everything you have done. It has been a pleasure of building Moderna with you and the team. I look forward to continuing working with you in the coming quarters.

The company has retained Russell Reynolds to recruit a new Chief Medical Officer with global and commercial experience as the company scale up to launch the COVID-19 vaccine, of course, around the world, also prepares for potential COVID boost and prepares to file several biological license over the next few years.

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

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Stéphane, and good morning, everyone. Today, I want to take you through our current thinking on variance 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 neutralizing activity against all variants of concern tested to date. Nonetheless, as recent reports have increased transmission and potential reinfections of the new variants have emerged, 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 original strains appears to be relatively weaker against the B.1.351 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 strains. 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 TeenCOVE Phase II/III study in adolescents ages 12 to 17 years is ongoing and recently completed enrollment. The KidCOVE 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 variant studies, we plan to test a variant-specific booster candidate, mRNA-1273.351 based on the B.1.351 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. And we're also evaluating a third 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 the next-generation vaccine, mRNA-1283 that encodes for the receptor binding domain and end terminal domain of the spike protein and is being developed as a potential refrigerator stable mRNA vaccine that could facilitate easier distribution and administration in a wider range of settings, including potentially developing countries.

We believe messenger RNA is best positioned to address the potential threat of SARS-CoV-2 variance, given several key characteristics, including high vaccine efficacy, speed and agility to make updates, 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 have shipped 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 - *Moderna, Inc. - Chief Medical Officer*

Thank you, Stephen. So let me briefly summarize where we are in the rest of our pipeline. With 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, 1 in children and 1 in adults. The pediatric trial is enrolling quickly, and the first 3 cohorts in the age de-escalation 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 4 seasonal viruses recommended by the WHO, eventually moving 1 candidate into a Phase III trial.

Our HIV vaccine program has 2 approaches. mRNA-1644 is a collaboration with IAVI and the Bill and Melinda Gates foundation. It's a novel approach to an HIV vaccine strategy that's designed to elicit broadly neutralizing HIV-1 antibodies. mRNA-1574 is a collaboration with the NIH, and this includes multiple native-like trimer 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 a 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 upsized head and neck cohort that is currently recruiting additional patients.

The KRAS Phase I that is partnered with Merck continues. And in the intratumoral oncology, we have a Phase II ongoing with OX40 ligand program in ovarian cancer patients. The Phase I dose escalation for the triplet program is ongoing both as monotherapy and in combination with durvalumab. And IL-12 partnered with AstraZeneca continues in a Phase I trial. Finally, within the systemic intracellular therapeutics, the Phase I/II 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 Stéphane.

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

Thank you, Tal. On Slide 32. We have a set of clear priorities for 2021, and everybody at Moderna has had a chance to review them and to discuss them.

Priority #1, to maximize the impact of our COVID-19 vaccine. The output in 2021 in terms of number of dose that we can ship to countries, the manufacturing scale-up, preparing for 2022 supply, clinical development of variants and boost, and our full commitment to bring variants of concern to the clinic. Priority #2, accelerate vaccine development and continue to bring more innovation from a research lab to clinical development.

Priority #3, generate proof-of-concept in therapeutics, based on the success of our ability to repeat dose in human of therapeutics technology with chikungunya antibodies. But also with intratumoral, we expect key data in cardiology, oncology, rate genetic disease and the entry in 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 are still at the beginning of the S-curve of this exciting new disruptive technology.

On Slide 33, as I shared earlier, this is an important inflection year for the company, now that we know that mRNA vaccine can be approved, that we have positive cash flow, we have the ability to invest and to scale like we've never had in our history.

If you look at Slide 34, you see some of the key attributes that energized me. mRNA is an information molecule, Moderna has a unique platform. We have a very strong cash position. We have signed very large amount of APAs. 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 with Lonza, Catalent, ROVI, (inaudible). We have already made 100 million doses of drug substance of the COVID-19 vaccine. We have shipped approximately 60 million doses globally. And as the team reviewed, we have 24 exciting first-in-class or best-in-class development programs that we are pushing towards the clinic -- sorry, for approval.

As our historic investors know, since I've 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 were focused on moving mRNA-1273 to Phase I, Phase II, Phase III regulatory authorization and on building manufacturing to deliver up to 1 billion doses for 2021.

We did not spend much time asking how do we grow 10x? We were focused on how do we get this important vaccine to the finish line and get up to 1 billion dose to help 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 engaged with the Board and some of our executive team members and asked all of them, "Now that we know mRNA vaccine can get approved and that we are generating cash, how do we grow 10x from here?"

The last 2 months have been really fun to invent 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 to 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 our regular investor events. We will host our Vaccine Day on April 14. We will host our annual Science Day on May 27. And we will host our annual R&D Day on September 9.

More than ever, we have a 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 build the best version 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 questions. Operator?

QUESTIONS AND ANSWERS

Operator

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

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

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 you think about the probability of using a lower dose there.

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

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

Go ahead, Stephen.

Stephen Hoge - *Moderna, Inc. - President*

I'll take the -- I'll try and take the first one and then hand it over to Tal as well. And then I think David will obviously take the second.

The -- so first on 50 microgram, I'd remind you of a couple of things. So in this case, this 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've shared our Phase II 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.

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

This is Tal. The only thing I'd add is that, that has scientific precedence. There's been data, I believe with a 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 priming series could suffice. Recall that our dose at 100 supersedes what you see with natural infection in terms of neutralizing antibodies to begin with.

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

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 the process, as we've had the lots made and being able to see the demonstrated output. I think it's important to always appreciate this is a new [technology] we have never made and nobody in the world has made at that scale so fast.

And so it's important for people to understand, we invested and built the manufacturing capacity, the ability to make 1 billion dose. The piece, having worked myself in manufacturing at commercial scale, and of course, you know Juan Andres, who runs manufacturing -- used to run manufacturing for Novartis worldwide, there are so many unknown at this stage that as we learn more, we are upgrading our numbers. As you know, last year, early in the process, we said we feel comfortable we'll get at least 500 million dose of the 1 billion of infrastructure capacity.

Then we raised it to 600. With what we have seen out of the U.S. supply chain, the -- as you know, Europe is around 3 months behind the U.S. because of when we started building it. We did not have a Norwood-like site in Europe, as you know. We feel good about what's happening in the U.S. The team are doing really a remarkable job. And so we feel comfortable today to up what we call our base case. We feel very comfortable that we will deliver 700 million doses.

The team is working extremely hard to get to 1 billion dose. They know that every extra dose we can get out of Moderna supply chain will be used and will help protect people. So you have our full commitment to do everything we can to get as close as we can to 1 billion. But at this stage, what we're saying is we feel very comfortable we can deliver 700 million, base plan. And we are still working through the 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.

Operator

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

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

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?

David W. Meline - *Moderna, Inc. - CFO & Principal Accounting Officer*

Yes. So the $200 million of revenue was associated with the deliveries that we made to the government in the fourth quarter in the U.S., which was around $17 million.

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

And Ted, this is Tal. As it relates to the triplet, I hope so. Data in 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 focus on it.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

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

Operator

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

Salveen Jaswal Richter - *Goldman Sachs Group, Inc., Research Division - VP*

And Tal, I want to second that. Good luck with the path ahead, and you will be missed here.

So with regard to variance, which of 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? You did mention options. So I'm just curious how we should think about that.

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Salveen. I'll try and take the first part of that for those questions. So as far as what's 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 third 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 a vaccine that provides the broadest immunity, so not just against ancestral strains or a boost against the new strains would perhaps be 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.

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

Thanks, Stephen. And on the pricing question, Salveen, at this stage, we have not disclosed any information on pricing. The piece that I can share as just color is, 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 versus other technologies and other companies. And so in due course, as the 2021 year progress, we'll be sharing more color on the pricing strategy for 2022 when for both of the prime series as well as the variant. It might be the same, it might not be the same. So we'll discuss that in due course. Thank you.

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

And Salveen, this is Tal. Thanks for your kind note. And I wanted to answer your question about the correlate. I think that work continues. It's being primary 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 correlative protection, it 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 that. So we continue to work towards that goal. We'll see in the coming months whether when one emerges.

Operator

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

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

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? That's just question 1 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 vaccines for mRNA versus adeno, particularly with multiple streams in there? How do you think about comparing and contrasting?

Stephen Hoge - *Moderna, Inc. - President*

So maybe I'll take the first part of it and then hand over to Tal for the second. I think the -- 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 to when we announced that we started manufacturing, it might be even faster than last year.

We do think the clinical program for testing 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. Then we'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 Stéphane noted, our manufacturing systems, 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 a booster.

Tal, do you want to take the second part of that?

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

Yes. That's a softball. Look, the mRNA, the beauty of the mRNA technology is the fact that the immune system doesn't recognize the LMPs per se. It only recognizes the protein that we teach the body 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 mRNA or, frankly, an adenovector.

I think the challenge with the adenovector is 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 adenovectors, you can get a boost, but the magnitude of that boost is invariably less than the magnitude of the boost you get with an mRNA platform. And that is true just in the first boost. I suspect that if you needed to come with a third dose or a fourth dose or variant-specific vaccines, it would be challenging to get the requisite amount of specific immune recognition towards the new transgene.

Operator

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

Huidong Wang - *Barclays Bank PLC, Research Division - Research Analyst*

Tal, good luck with your next journey. It's a big shoe to fill, and you will certainly be missed here. I have 2 questions regarding the variance and also next-generation COVID vaccine 1283. So for 1283, is it shorter sequence that make freezer storage feasible? And also with the sequence outside of RBM sequence -- RBM multi sequence?

And then the second part of the question is the COVE II variant for the NIH study. I wondering if you can give a little bit more color regarding type of subjects you will enroll, whether it's a vaccine-naive or experienced subjects and also the booster timing.

Stephen Hoge - *Moderna, Inc. - President*

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. As you'll know, we've had advantages on our mRNA platform based on our long history of working in it, for instance, that we're functioning right now already, as has been noted, in a normal freezer for up to 6 months and actually already doing 30 days with mRNA-1273 in a refrigerator post stalling. And so it's a benefit that we're already well on that path, even with just 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 has been widely reported, those are particularly important for neutralizing activity in the immune system against SARS-CoV-2 virus.

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

Thanks, Stephen. 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 they launch it. But in essence, the answer is both. They will have arms there that will be testing the new variant vaccine as a boost in those who have been previously immunized on their Phase I trial. And then there will be a component that will test the new vaccine in a primary series.

Operator

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

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

And all the best to Tal, although it's good to know we'll have you for a couple more quarters. So 2 questions for me as well. Look, I realize there's 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 of 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 U.S. 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 of sales? And if so, should we just be assuming a generally stable rate going forward? Are those changed at all?

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

So there's a lot to unpack here. 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 $3 per dose. And as you know, we walked you through our pricing strategy back, I think, in August, on the Q2 call. The Moderna vaccine is priced much higher.

And I think it comes down to a few things. And the most important one is efficacy. Governments care about saving lives. Governments care about getting the economies back on their feet. And so what we're hearing from governments, literally almost on a daily basis as we engage with our existing government contacts versus new ones that are calling us, is -- there starts to be very clear differentiations between the different products that are either available already or that are getting very close to authorization.

And I wish, if I had a crystal ball last year, that we would have built more manufacturing capacity for '21. But I did not anticipate and I don't think anybody did that there will be such difference of efficacy between vaccine, that the mRNA vaccine will be such high performance. As you know, some countries decided to invest first to procure vaccine in adeno or protein technology because they were better understood. And as we know what happened in 2020 in terms of the clinical data, that has played a big role.

So it's quite interesting that -- also seeing 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 U.S., we have as of today, I'm hopeful this will change soon with VRBPAC meeting tomorrow, but only to mRNA vaccine authorized in the U.S.

But if you look at what's happening in some countries in Europe, also what's happening in different countries around the world, I think governments, because of essence, advisers and clinical advisers and because of really the aim to reduce the pressure on the health care system, in the hospitals.

Also what is quite fascinating, and I'm sure you're all observing it, is that, at least 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 are all over the news every day. This has never happened to my knowledge for any of our products.

And so you have this very interesting phenomenon that's happening too, that you have the clinicians, the nurses, the pharmacists, but the consumers too, that are believing that those products are not all the same. And this, I think will be a very important differentiation as we move into '22, as we move more to a traditional commercial market, where it's not governments buying directly, but the traditional kind of retail channel. And the impact, I think, of the consumers' desire to ask for a product when he or she walks into a pharmacy or their GP's office will be quite significantly different from what we are used to with other products.

David W. Meline - *Moderna, Inc. - CFO & Principal Accounting Officer*

Okay. Maybe then I'd comment on the question about cost of sales. So 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%, because we feel confident that, that's the right range, right zone that we're in. And yes, 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.

Operator

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

Geoffrey Christopher Meacham - *BofA Securities, Research Division - Research Analyst*

Also I wanted to offer up best wishes to Tal. A question on manufacturing investments, I guess, for Stéphane. So I guess I'll focus on variance with the booster. And clearly, you guys have to fund many assets progressing in the pipeline. But how flexible are your manufacturing investments? I guess the question is, as the cases globally continue to decline, is there a way to scale back some of that capacity should lower volumes become the norm?

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

Those are great questions. So in terms of the flexibility, as I described in my remarks, the only raw material that is different from let's say mRNA-1273 to mRNA-1273.351 is only the plasmid. The enzymes are the same, the lipid is the same, with 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 with recombinant, like I used to do at Lilly. And as you know, I trained as a biochemical engineer, doing neutrophil and E. coli production in bioreactors. It is literally, you come a week after we use disposable reactors, you get new consumable plastic bags and so on as your reactor. And here you go again, you just need to change -- take a different plasmid. Because we use disposable reactors and not stainless steel reactors you don't have to spend a lot of time doing cleaning, validation because we basically dispose of things.

And so the flexibility is quite incredible. You just need a new plasmid. And so because -- so it's not a very expensive part of the cost of the total cost of the finished product that is filled in a vial, because you have to make the mRNA, you have to formulate it and you have to fill it in a vial, our doing a lot of plasmid at risk for variant is a great optionality for the company with very, very [seldom] payment.

So that's a piece that I think makes this technology very unique on the ability to scale and be able to be flexible to respond to different demand. Is there a world where we potentially might end up with a different combination of mutant boost on the road in different continents? Maybe. I don't know, again, it will 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 and at the speed, which is, I think will surprise many. Because again, we make these other products in the same reactors.

In terms of taking down the manufacturing capacity if we don't need, let's say, in '23 or '24, the same amount of volume because of a mass of boosting, as we say, it's actually interesting because, as you know, we have now good plants where we have quite a lot of capacity. But also, we have some capacity at Lonza, in New Hampshire and also capacity in Switzerland, where they have there several lines of manufacturing. So we have actually quite a lot of flexibility to take capacity down at Lonza, either in the U.S. 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 to understand why actually us building manufacturing to that scale is going to be so enabling to Moderna to keep growing and growing and growing.

First is the other vaccines. CMV is ready to move into Phase III, as we said this year. We will give you updates on the flu program, but I will remind everybody that there is an approvable endpoint with the regulator for seasonal flu vaccines. And so we anticipate that the development of the flu program will be pretty quick.

And as we discussed on previous calls, one of our kind of optimal target product profile for down the road will be a product that is both seasonal flu, with the current strain of flu, but also a boost for COVID-19 with the relevant strain at that time in the same dose. So we anticipate we should have high efficacy for flu as much as mRNA virus. It's a pretty straightforward virus like the SARS-CoV-2 virus.

And so that is where we are going. We have more vaccines coming to the market. And then there's also our therapeutic pipeline. And the piece, I think, that is actually quite good for us that we started with vaccine, the scale-up, is I go back to mass, which is if you think about some of our products, as you know 1273 requires 100-microgram per human per dose. But if you look at the chikungunya antibody program, that use the IV-formulated mRNA that we use also in the rare disease program, for example, what we showed is very good data at 0.1 milligram per kilo. So in a 70-kilo adult, it is 7 milligram compared to 100 micrograms.

So as we move the therapeutic pipeline further into development, but especially to commercial, we're going to need much more mass of mRNA. And so I actually -- I'm spending a lot of time thinking, one, how do we keep adding capacity to manage the entire pipeline as it's progressing. We have the flexibility with Lonza, that's why we did it this way with Juan, so we are ready to take it -- take chunks down if we need to. But if I was a betting man, I would bet with you that we're going to be more adding than taking 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 we're able to do with both the pentamer and GB. And so I'm more spending time wanting to think about how do we do more.

Operator

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

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

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

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

Thanks. So as we've said all along, which is why we gave a range and not one number for expected supply in the year, I think one number is a very dangerous strategy. As we said, those type of consumables are, of course, important. We are in a regulated business, and we cannot start to make a product until we have all the components, all the raw material, the entire train team and so on and so forth. So we have a lot of -- like in an airplane, you have to check a lot of things before you can start the engine. Well, in GMP manufacturing, you have to do the same to ensure the quality and the safety of the product.

And so, well, I think the team has done a very good job last year. And 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, geez, this could turn into a pandemic. And we started to think bigger. And so, one, the team and I spent quite a lot of time as we were starting to think about, okay, how do we go -- if we had to make 1 billion dose in '21, how would we do that? I used to run the supply chain at Lilly globally. And we went right away to start to talk to our suppliers.

And one other 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, in some suppliers. Because the increase of mass of product we're ordering from them was so gigantic, a thousand times more, even 2,000 times more than the year before.

As you can imagine, many of them looked at us a bit funny and were very worried. They were worried that if the drug would fail, they might be in trouble, because they will have to get this type of increase of capacity to sometime, buy new equipment, hire more people, buy their own raw materials to make our 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 they will go and take that cash and start to invest to prepare for scale up. So we took a lot of business risk last year that we thought were necessary to ensure we could deliver this year on the output from the manufacturing supply chain.

So I think we're in a good place. Do we have from time to time, one component that give 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 away, 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 safety stock on site. So if your supplier has a bump in the road, a pump 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.

Operator

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

Simon P. Baker - *Redburn (Europe) Limited, Research Division - Head of Pharmaceutical Research*

Two, if I may, please. Firstly, just going back to cost of goods sold. You've helpfully 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 meaningfully below 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 road map 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?

David W. Meline - *Moderna, Inc. - CFO & Principal Accounting Officer*

Yes. 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 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 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.

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

Thank you, David. So let me take the CMV question. So a few bit of colors on the $2 billion to $5 billion annual peak sale estimate that we talked about now a while ago. We talked about that as a company that never had run a Phase III at the time, that had never launched a product or get a product approved at the time, that had 0 commercial employee at the time. So we did the analysis with an outside commercial consulting 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 credibility in life has to be earned. And so I will just make the analogy to manufacturing in the sense, we built 1 billion of 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 should get at least 500 million dose out. And then as we learned more, we moved it to 600. And as we learned more, we moved it yesterday to 700 million.

So do I believe it is possible as we're going to sell more than 5 billion of CMV? Yes, I believe it's possible because it's an incredible unmet medical need. As the world develops, I think the piece one has to be careful about peak sales is peak sales when peak sales slightly up (inaudible) peak sales 25 years after launch because those vaccines are like annuity-like products. There's, of course, inflation. There's, of course, developing countries that are becoming richer and richer. So is there upside to the number? I believe there's upside to the number. But that's our number right now as a company.

Operator

Our next question comes from the line of Mani Foroohar with SVB Leerink.

Mani Foroohar - *SVB Leerink LLC, Research Division - MD of Genetic Medicines & Senior Research Analyst*

Tal, looking forward to chatting with you later on today in our fireside chat, and excited to hear at some point what your next adventure is going to be.

A quick and sort of boring financial question. As we -- as you guys are pretty clearly going to transition to profitability, cash flow positivity on a -- at least in the near term, very durable basis, when would you consider changing your current treatment of your NOL allowances? How would that -- how would you communicate that? How would that flow through how you communicate your financials from a 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 and the other mRNA vaccine, that titers appear to improve over time and cellular immunity improves over time and the gap in efficacy against the so-called South African variance and the ancestral Wuhan variant seems to close. That would suggest to me, that 1273 should have similar efficacy versus the South African and the Wuhan variance. Am I interpreting it the same way you are? Or am I missing something?

David W. Meline - *Moderna, Inc. - CFO & Principal Accounting Officer*

Yes. So maybe I'll 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] pretax income. And it's likely based on the current book of business that we would consume during the year the entire loss carryforward. So that's point one.

Point two is from an accounting perspective, what happens is you basically project the 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 will -- it would be stable unless we have some other changes that caused the full year rate to change as we move forward. Hopefully, that's clear.

Mani Foroohar - *SVB Leerink LLC, Research Division - MD of Genetic Medicines & Senior Research Analyst*

That's clear. I misstated my question. I actually meant versus severe disease mortality in terms of the similarity and efficacy alone. I thought of a longer-term follow-up.

Stephen Hoge - *Moderna, Inc. - President*

Sure. Yes. So thank you for that question. So let me take a stab at it. I think we're -- as you noted, I mean, we had nearly or essentially 100% of efficacy against severe disease, 94% against 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 virulent, 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 coronaviruses, that's what happens. The durability here has always been a question. Is it 1 year? Is it 3 years? Is it 5 years? I think as you see new strains emerge, like the potentially concerning strains that we've been talking about, particularly in the Republic of South Africa and Brazil, you have to ask the question, is that -- what does that look like not just now, but what does that look like 6 months from now, 1 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 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 -- 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 it's going to continue to be something we have to track closely as we look ahead.

Mani Foroohar - *SVB Leerink LLC, Research Division - MD of Genetic Medicines & Senior Research Analyst*

That's helpful. I guess that would imply also that it might be useful to look at sero collected from the already vaccinated patients, 180, et cetera, further days out and perhaps perform the same experiment described in the New England Journal of Medicine article. Would you consider disclosing that data? Or do you think it just makes more sense to just move to your novel variant approaches? And just would the clinical data speak for itself?

Stephen Hoge - *Moderna, Inc. - President*

So fair question. I mean, look, I think we will obviously update data on durability of responses across our Phase I, Phase II, Phase III 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 variants and strategies against it is -- I think none of us want to be in a situation where we wait until there are reinfections and increased morbidity and, God forbid, more mortality in a seasonal epidemic, for instance, this winter in the Northern Hemisphere, this coming winter. And then say, okay, now it's time to be boosting people.

And so as we're continuing to face an evolving 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'll continue to follow things like the data that you pointed to, which is how are we doing in terms of immunity and blood of people who've previously been vaccinated or previously infected. We'll obviously closely be following reinfections. 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 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 in the concerning phase of this epidemic or pandemic or is it a place where we start to get more and more confident that the vaccines have the virus under control.

Operator

At this time, I'll turn the call back over to Stéphane Bancel for closing remarks.

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

Well, thank you very much, everybody, for joining us. We look forward to seeing you at our next event on April 14 for Vaccine Day, and I wish everybody to stay safe. Have a great day. Bye.

Operator

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