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MRNA.OQ - Q2 2022 Moderna Inc Earnings Call

EVENT DATE/TIME: AUGUST 03, 2022 / 12:00PM GMT

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PRESENTATION

Operator

Good morning. My name is Kevin, and I'll be your operator today. Welcome to Moderna's Second Quarter 2022 Earnings Call. (Operator Instructions) Please be advised that this call is being recorded.

At this time, I'd 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, Kevin. Good morning, everyone, and thank you for joining us on today's call to discuss Moderna's second quarter 2022 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 Chief Executive Officer; David Meline, our Chief Financial Officer; Stephen Hoge, our President; Paul Burton, our Chief Medical Officer; and Arpa Garay, our Chief Commercial 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.

With that, I will turn the call over to Stephane.

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

Thank you, Lavina. Good morning or good afternoon, everyone. Welcome to our Q2 2022 conference call. Today, I will start with a quick business review before Paul walks you through some new real-world evidence data on Spikevax. And then Stephen will review our clinical programs. Arpa

will take you through commercial dynamics, and David will present financials. I will then come back to close, share some thoughts about where we're heading.

In the quarter, we continued strong financial performance. We reported revenue of $4.7 billion and net income of $2.2 billion. We were pleased with the Q2 sales. The decrease in net income is driven by higher cost of sales in the quarter, mostly driven by our COVAX contract, David will call that in the financials; a strong increase in R&D investments to fund our future, including the 4 Phase III programs; and the higher tax rate than Q2 2021.

Through our share repurchase program, we reduced our share count by 9 million shares in Q2. Since the start of our first share repurchase program in 2021 through yesterday, we have repurchased around 18 million shares. We continue to have signed advanced purchase agreement for expected delivery in 2022 in the amount of approximately $21 billion.

Based on our commercial momentum and our balance sheet, today, we also announced that our Board of Directors has approved a new share buyback program for an additional $3 billion.

Let me now review the business and pipeline update since our last review. I am pleased with the important progress the Moderna team has made on advancing the pipeline closer to product launches and increasing the breadth of the pipeline.

On the commercial side, we recently signed a new agreement with the U.S. government for an initial 66 million doses for bivalent booster vaccine against Omicron. The agreement also includes options to purchase an additional 234 million doses, putting the total sales potentially up 400 million doses. The U.S. government has already exercised option for an additional 4 million doses since the contract was signed and announced. So the current total is actually 70 million doses contracted for the fall of 2022 with the U.S. government.

In addition, both Canada and the U.K. had exercised options for their current agreements for additional deliveries in 2022.

On the regulatory front, I am very happy to have Spikevax authorized for pediatric and adolescent population in the U.S. This (inaudible) efforts with regulatory clinical teams at Moderna and the U.S. FDA allows the protection of the young in the U.S. population as they head back to school.

Health Canada and Australia have also authorized the use of vaccine for children 6 months to 5 years old.

Our research and clinical team continued the momentum in our pipeline. We have 4 programs in Phase III development with COVID bivalent booster, flu, RSV and CMV trials ongoing. Importantly, our Phase I study with mRNA-1020/1030 of 2 vaccines targeting the traditional flu antigen as well as the novel antigen is now fully enrolled. And our combination flu plus COVID vaccine is also fully enrolled for its Phase I/II. We look forward to this readout on safety and immunogenecity for our programs.

In properties, we now have an open IND with our checkpoint vaccine in oncology, and we dosed our first patients with our GSDA1 rare disease program.

Finally, we are very pleased to be on track and look forward to sharing data for our proof-of-concept studies this year for 2 operative programs. The Phase I/II for a rare disease program, propionic acidemia or PA and our Phase II data with our personalized cancer vaccine in combination to KEYTRUDA versus KEYTRUDA monotherapy.

Slide 6 is our usual snapshot of Moderna in August 2022, showing the breadth of the pipeline with 46 program development across vaccine but also therapeutics. The company has a strong foundation. We run a 3,400 teams and growing, 11 commercial subsidiary and a strong balance sheet with around $18 billion of cash to fuel our growth.

I will now hand it over to Paul.

Paul Burton - *Moderna, Inc. - Chief Medical Officer*

Thank you, Stephane, and good day, everyone. As the COVID-19 pandemic continues and the SARS-CoV-2 virus keeps undergoing significant evolutionary change, the subject top of mind for many people is boosting, when to get boosted and what to get boosted with. In the next few slides, I want to show you how the Moderna mRNA-1273 vaccine is performing clinically in the booster setting and how antibody levels are performing in the real-world setting in individuals primed and boosted with mRNA vaccines.

Here in this next slide, you see the rates of COVID-19 infection in over 3 million individuals in a Spanish National Registry. The first point this data make is that boosting is highly effective, reducing the risk of infection. The second point the authors make is that mRNA-1273, the Moderna vaccine, is more effective than BNT162b2 and that the effect size increases over time.

In the second example, I'm showing you data from the U.S. VA system in over 450,000 individuals boosted with either mRNA-1273 shown here in green or BNT162b2 shown in red. Again, in terms of infection or hospitalization prevention, the authors conclude that mRNA-1273 is more effective than the alternate mRNA vaccine.

Finally, here are data from over 3 million individuals in the NHS England database, again, showing a clinically meaningful and statistically significant reduction in COVID-19 infection and hospitalization with mRNA-1273 boosting compared to BNT162b2 during the Omicron period of infection.

I want to turn now to data from an innovative, decentralized, pragmatic, real-world study we have recently conducted within the Moderna community, a collaborative platform with Evidation of over 100,000 participants here in the United States. The study is called disCOVEries, and it enrolled approximately 850 of these people into a real-world assessment of antibody levels, following primary vaccination and boosting with either Moderna-Moderna-Moderna, that's the MMM group, or Pfizer-Pfizer-Pfizer, that's the PPP group. Importantly, the study population has an average age of 44. Approximately 60% of the participants are female, and it's ethnically very diverse. Participants were enrolled into the study, consented and received a home self-administered microneedle blood collection kit from your buyer.

As you can see here across an array of SARS-CoV-2 variance of concern, higher and more durable antibody levels shown here on a logarithmic Y-axis scale were observed in those individuals primed and boosted with the Moderna vaccine in red relative to the Pfizer vaccine in blue from 8 weeks through 32 weeks following their first booster. Many of the comparisons were highly statistically significantly different. It's true, even for antibody levels against the Omicron BA.1 variant of concern, where an approximately 12-week duration advantage is seen in Moderna prime and boosted individuals compared to those receiving the Pfizer vaccine.

So taken together, these data demonstrate the strong performance of the Moderna vaccine in a real-world clinical boosting setting, which could be explained by higher enduring antibody levels against a wide variety of variants of concern.

I will now turn the call over to Dr. Stephen Hoge to provide comments regarding the composition of the 4 COVID-19 booster vaccines as well as other pipeline updates. Stephen?

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Paul. Good morning or good afternoon, everyone. I will quickly review some of the recent updates around our Omicron-containing COVID booster for the upcoming fall season, and then review the rest of our pipeline before handing it to Arpa.

We are advancing 2 bivalent candidates for the fall/winter season of 2022 to meet different market demands. MRNA-1273.214 is our Omicron BA.1-containing bivalent vaccine. Clinical data previously presented from our Phase II/III study showed that 214 significantly increased neutralizing titers against BA.4, BA.5 compared to the currently authorized booster. Following regulatory discussions, we have submitted application for authorization for 214 in the EU, Australia, U.K., Canada and Switzerland. We have also started a rolling submission in Japan.

mRNA-1273.222 is our bivalent vaccine candidate that combines an Omicron-containing vaccine based on the BA.4, BA.5 subvariant and our original mRNA-1273. The FDA has asked us to submit for authorization for 222 based on the demonstrated strength of our bivalent platform against variants

of concern, including data from our Phase II/III studies with 214 and 211 bivalent boosters. FDA has also advised manufacturers to initiate clinical trials with 222 as these data will serve useful as the pandemic continues to evolve. We expect to start this trial in August.

Now to review our respiratory vaccine pipeline on Slide 16. I just went over our Omicron-containing COVID boosters. We were happy to announce that our flu vaccine, mRNA-1010, launched an immunogenicity study in the Southern Hemisphere in June. And we are also preparing to launch an efficacy study for mRNA-1010 this upcoming fall, which will either serve as a post-approval efficacy study or, if we are not eligible for accelerated approval, will support our application. Our next-generation flu vaccines, which have 8 mRNAs across HA and NA antigens, our mRNA-1020 and 1030, also completed enrollment in their Phase I/II study. Our RSV program is ongoing, including a Phase III in older adults and a Phase I in pediatrics.

Importantly, we also started and completed enrollment for the Phase I/II study of our COVID + flu vaccine this quarter. We look forward to sharing that data when we have it.

Our combination COVID + flu + RSV vaccine also expects to enter the clinic this year. Our endemic human coronavirus vaccine is in preclinical, along with our pediatric RSV + hMPV combination vaccine. And the pediatric hMPV + PIV3 vaccine Phase Ib is now fully enrolled.

Moving on to our latent and public health vaccine portfolio. our CMV vaccine is ongoing in a Phase III. Our EBV vaccine to prevent infectious mononucleosis is in a Phase I study. And our EBV vaccine to prevent long-term sequelae from the virus is in preclinical. We have 2 HIV Phase I trials and a Phase II Zika vaccine trial that are all ongoing. Our phase -- our HSV and VZV vaccines are in preclinical. And finally, we dosed the first participants in our Phase I study of our Nipah vaccine, which is being conducted in partnership with the NIH.

And to close on our therapeutics pipeline on Slide 18. Stephane already mentioned that we expect data from our proof-of-concept studies in our PCV and PA programs later this year. A few other important updates to highlight on this slide. First, we were happy to dose our first patient in our GSD1a trial and open an IND for our checkpoint cancer vaccine. Second, AstraZeneca notified us that after a portfolio review, they are returning the VEGF program and we are currently evaluating the next steps for that asset. Finally, based on a review of early clinical data from our IL-2 program for autoimmune disease and the evolving competitive landscape, we've decided to discontinue further development of our program and we'll remove it from our pipeline.

With that, I'll hand it over to Arpa.

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

Thank you, Stephen. Good morning and good afternoon to everyone. As the newest member of Moderna's Executive Committee, I'm excited to see the impact that we've had in COVID as well as the commercial opportunities ahead for us in COVID as well as future vaccines and therapeutics in the long run leveraging our mRNA technology.

Turning now to Slide 20, where you will see the regional sales mix in second quarter and in the first half of 2022. In the quarter, North American sales were $1.6 billion. These sales were driven by 1273 booster deliveries to the United States as we continue to fulfill our first U.S. government order, with the vast majority now delivered through the end of second quarter this year. In the quarter, we also delivered primary series doses for the pediatric group 5 years and younger as the authorization for this group came through in this quarter.

Sales to EMEA were $1.5 billion, and sales to Asia Pacific were $1.1 billion. As you can see across the first 2 quarters of the year, North American sales were $2.7 billion, sales to EMEA were $3.9 billion and sales to Asia Pacific region were $3 billion. Of note, for both the 3- and 6-month periods, we saw a geographic diversification of sales across these key regions. This diversification is a reflection of how quickly we built out and executed within our global commercial organization.

Now turning to Slide 21. We're also happy to see that as we continue to scale globally around the world that Spikevax's market share in the booster market, defined as a third or fourth booster dose, continues to show substantial market share.

As Stephane has already mentioned, we see on Slide 22 our new U.S. government contracts for the fall of 2022. Specifically, the agreement initially was for 66 million doses of our bivalent COVID booster to be delivered in 2022. Earlier this week, the U.S. government informed us that they exercised an option for 4 million doses for the pediatric age group. This brings the total contract value to approximately $1.8 billion. Our U.S. government order includes options to purchase an additional 230 million doses, bringing the total to 300 million doses if all options are exercised. As you heard from Stephen earlier, as per FDA guidance, the U.S. fall booster product will be the mRNa-1273.222, which consists of 1273 and the Omicron BA.4/5 subvariant.

I'd like to now spend some time on the evolution of the pandemic and the resulting impact on the commercial outlook. Early in the pandemic, we anticipated several factors, including the virus' evolution, population immunity at any given time and seasonal trends, would result in a shift to the endemic setting. And we've shared this illustrative graph before. These same factors have and will continue to influence the commercial outlook.

With the emergence and then dominance of multiple variants at different time points, we have been able to develop boosters to address these variants, which includes our bivalent boosters against the Omicron variant. We are currently advancing 2 bivalent booster candidates for the fall of 2022 based on different market needs. The 2 bivalent booster candidates we're advancing are the mRNA-1273.214 and mRNa-1273.222. Both contain 25 micrograms of the currently authorized booster 1273 and 25 micrograms of an Omicron subvariant, either BA.1 or BA.4/5. Deliveries for these boosters will start in September this year and will be more heavily weighted to the fourth quarter as we ramp manufacturing and obtain regulatory authorizations around the world.

And to close, as we look to 2023, we are prepared for a shift to the commercial market in the U.S. for COVID boosters where the market will be more fragmented than it was during the pandemic where the U.S. government was the sole purchaser of vaccines. The commercial organization has already engaged with commercial payers and the channel, both channel distributors as well as key pharmacies, in anticipation of this shift. Internationally, we expect public health authorities to remain key purchasers of vaccines, but we are also identifying markets where there may be a private commercial market as well. All in all, we are well prepped for the transition as we have invested in building our commercial infrastructure, both in the U.S. and globally.

With that, I will turn it over to David.

David W. Meline - *Moderna, Inc. - CFO*

Okay. Thank you, Arpa. Today, we're providing the analysis of actual 2022 second quarter results along with a view of key drivers of financial performance going forward. Overall, we continue to progress well, and I'm very pleased with our operational and commercial performance.

Turning now to Slide 25, starting with an overview of our financial performance in the second quarter. Total product sales for the second quarter of 2022 of $4.5 billion increased by $334 million or 8% compared to the prior period. The total product sales growth in 2022 was primarily driven by higher average sale price of our COVID-19 vaccine due to changing customer mix. Total revenue was $4.7 billion for the second quarter of 2022, an increase of $395 million compared to Q2 of last year, driven by the increase of sales of our COVID-19 vaccine.

Cost of sales was $1.4 billion or 30% of product sales in the second quarter of 2022 compared to 18% of product sales for the same period in 2021. This includes a charge of $499 million for inventory write-downs related to excess and obsolete COVID-19 products, a loss on firm purchase commitments of $184 million and an expense for unutilized external manufacturing capacity of $131 million. These charges are driven by a substantial reduction of our expected deliveries to COVAX as indicated as a potential variable impacting our advanced purchase agreements in our last call and, to a lesser extent, by deferral of deliveries to other customers, particularly to the European Union in light of the expected upcoming launch of our updated bivalent vaccines.

Research and development expenses were $710 million for the second quarter of 2022, an increase by $289 million or 69% compared to the year ago period. The increase in R&D spend continues to be driven by clinical trial expenses, particularly with our COVID-19 and RSV programs as well as personnel-related costs for our expanding and maturing development portfolio.

Selling, general and administrative expenses were $211 million for the second quarter of 2022, increased by $90 million or 74% compared to the year ago period. The growth in spending was driven by the commercialization of our COVID-19 vaccine globally with continued investments in personnel and outside services in support of the accelerated company build-out.

The effective tax rate for the second quarter of 2022 was 11% compared to 9% for the same period in 2021. Let me remind you of the fact that we have a net operating loss carryforward of $2.3 billion at the end of 2020, which resulted in a nonrecurring benefit to the reported tax rate last year.

After-tax net income in Q2 2022 decreased by $583 million or 21% to $2.2 billion compared to the same period in 2021. The decrease was primarily due to higher cost of sales and other operating expenses in the current period.

Diluted EPS in Q2 2022 decreased by $1.22 or 19% to $5.24 a share, which is compared to the same period in 2021.

Turning now to year-to-date financial results compared to the prior year on Slide 26. Total product sales for the first 6 months of 2022 were $10.5 billion, increased by $4.5 billion or 76% compared to the prior year period. The total sales growth in 2022 was mainly attributable to our manufacturing capacity ramp-up and, to a smaller extent, to a favorable customer mix resulting in increased average selling price.

Total revenue was $10.8 billion for the first 6 months of 2022 compared to $6.3 billion in the same period in 2021. The increase in total revenue was primarily driven by the increase of sales of our COVID-19 vaccine outside of the U.S.

Cost of sales was $2.4 billion or 23% of product sales for the first 6 months of 2022. This compares to 16% of product sales in the prior year period on a reported basis or 19% adjusted for prelaunch inventory costs, which were expensed in 2020. The increase in cost of sales as a percent of product sales was mainly due to higher write-downs for excess and obsolete inventory expense and expenses related to future purchase commitments and unutilized external manufacturing capacity and, to a lesser extent, the lack of prelaunch inventory benefit that was realized in the first quarter of 2021.

Research and development expenses were $1.3 billion for the first 6 months of 2022, an increase of $442 million or 54% compared to the prior year. The increase in R&D spend continues to be driven by clinical trial expenses, personnel-related costs and outside services for expanding and maturing development portfolio including the development of our COVID-19 bivalent boosters.

Selling, general and administrative expenses of $479 million for the first 6 months of 2022 increased by $281 million or 142% compared to the year ago period. The growth in spending was driven by the commercialization of our COVID-19 vaccine globally and support of the accelerated company build-out, including substantial investments in digital. Additionally, in Q1 2022, there was an initial upfront endowment of $50 million for the newly established Moderna Foundation.

The effective tax rate for the first 6 months was 13% compared to 7% for the same period in 2021. The increase was primarily due to the benefit recorded in 2021 related to the release of the valuation allowance on the majority of our deferred tax assets.

After-tax net income increased by $1.9 billion or 46% to $5.9 billion for the first 6 months of 2022 compared to the same period in 2021. The increase in net income was driven by the growth of our product sales.

Diluted EPS for the first 6 months of 2022 increased by $4.55 or 49% to $13.85 compared with the same period in 2021.

Turning now to cash and cash deposits on Slide 27. We ended Q2 2022 with cash and investments of $18.1 billion compared to $19.3 billion at the end of Q1 of this year. The decrease reflects the share repurchase activities in Q2 of $1.3 billion. The ending balance of cash deposits for future product supply was $4.1 billion compared to $5.3 billion at the end of the previous quarter. The reduction quarter-over-quarter is driven by product deliveries against customer deposits.

Now turning to Slide 28. Our capital allocation priorities remain unchanged. Our top investment priority has been and will continue to be reinvesting in the base business across multiple areas. As previously stated, R&D spending was $1.3 billion in the first half of 2022, a 54% increase on a year-over-year basis. We remain on track with our full year R&D forecast of $2.5 billion to $3 billion.

Our second investment priority is to seek attractive external investment and collaboration opportunities to further expand the reach of Moderna's technology and capabilities. We are considering attractive opportunities that enable and complement our platform and take a disciplined approach in evaluating potential outside investments. We're in multiple active discussions regarding additional external collaboration opportunities.

After evaluating internal and external investment opportunities, we then assess additional uses of cash. In the second quarter of 2022, we repurchased 9 million shares for $1.3 billion. Since inception of our repurchase activities last year up until August 2, we have purchased 18 million shares or approximately 4% of our outstanding diluted shares for $3 billion in total.

As a reminder, we announced a share repurchase program for $3 billion in February of this year and currently have approximately $1 billion of remaining capacity from that authorization. As part of today's press release, we announced that the Board has authorized an additional share buyback program of $3 billion with no expiry.

Now let's turn to our 2022 updated financial framework on Page 29. We continue to have signed advanced purchase agreements for expected delivery in 2022 in the amount of approximately $21 billion. This includes expected sales from the recently announced new agreement with the U.S. government. And an adjustment for doses that remain unallocated by COVAX due to lack of demand, we indicated this was a possibility on our last call.

Furthermore, this total includes expected negative foreign exchange impacts compared to the contract value at signing, which we estimate to be approximately 1.5% of sales for the full year 2022, assuming current rates remain through year-end. We anticipate that for sales in the second half of 2022, sales will be greater in the fourth quarter than the third quarter driven by the timing of anticipated approval of our updated COVID-19 vaccines and the related manufacturing ramp-up of the new products.

Our total cost of sales includes the cost of goods manufacturer, third-party royalties as well as logistics and warehousing costs. We now expect our full year 2022 reported cost of sales to be in the mid-20% range, driven by the previously mentioned costs related to a reduction of doses to COVAX and deferral of doses to other customers. Cost of sales could increase to the high 20 percentage range in the event of further charges due to product updates.

For R&D and SG&A, we continue to expect full year expenses to be approximately $4 billion, driven by our maturing development portfolio and the global scaleup of the company. Based on current tax laws, we now expect our 2022 effective tax rate to be in the low to mid-teen range as a result of the benefits from the foreign-derived intangible income driven by our international business mix as well as stock-based compensation reductions.

Finally, regarding capital expenditures, we continue to plan for capital expenditures in the range of $0.6 billion to $0.8 billion as we further build out our manufacturing and general company infrastructure globally.

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

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

Thank you, David, Arpa, Stephen and Paul, for those updates.

In 2022, we set out to execute on 5 key priorities: First, to execute on delivering vaccine against $21 billion of signed advanced purchase agreement. With half of the year behind us and the signed deals for the fall of 2022 and our strong manufacturing team, we are on target.

We have continued the momentum in our late-stage clinical trials with our Phase III trials now in flu, RSV and CMV, and I thank our team for delivering on such aggressive time lines.

We are on track to share data from proof-of-concept studies from 2 therapeutic applications of our technology with data for our PA and PCV trial in second half. We have continued to make progress with new development candidates in vaccine and therapeutics. Some have already been announced and more will come in the second half of the year.

And finally, the recent announcement of our inhaled LNP with our partner Vertex, we've expanded our mRNA platform to target preliminary disease.

As we grow, we are committed to doing the right things in the right way for patients and our stakeholders. As a company led by a founding team, we are thinking in 5-, 10-, 20-year increments.

To that end, this year, we'll publish our very first ESG report, which highlights the key pillars of our corporate responsibility framework, medicine for patients, our employees, the environment, our community and, of course, governance. I'm proud of what we are doing initially at this pillar and so proud of the ambitious goals we set for ourselves. I believe that the first steps to achieving those ambitious goal is to set them, to create and foster a purpose-driven culture and governance framework to meet those goals.

As an example, our goal of a net zero carbon emission globally by 2030, we put Moderna among the global leaders in promoting long-term sustainable growth for our planet and our organization. We will share more detail on our ESG journey at our ESG Day on November 10. But first, we look forward to hosting you at our Annual Day of September 8.

Moderna's mission to deliver on the promise of mRNA science to create a new generation of transformative medicine for patients has always been our North Star. Despite the challenges in the financial market with concern on inflation and ensuing increase in interest rates and the cost of capital, Moderna is in a very fortunate position.

We have a unique mRNA platform, enabling the generation at unprecedented speed of innovative medicine. We have a strong team of 3,400 mission-driven employees. We have $18 billion of cash on our balance sheet and with a strong commercial momentum. We have no intention of slowing down our growth. We are putting our head down and doing the work. I have never been as excited about the future of Moderna. Now is not the time to slow down, patients are waiting for innovative medicine.

Thank you for listening, and now we'll be happy to take questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Matthew (inaudible).

Unidentified Analyst

Great. Stephane, I was hoping you could just maybe address in a little bit more specificity how you're thinking about opportunities for either acquisitions or collaborations. I think it's a topic that comes up a lot among investors, and I think there's a different scope that a lot of people think about including the things that are quite large versus things which might be more complementary on the technology side to the platform. So if you could just address how you're thinking about that in your priorities, that would be great.

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

Sure. Thanks for the question, Matthew. So as you know, we have [rated] now for over a year, our capital allocation strategy, that's in a cash flow positive situation. Priority number one, invest in the business; two, external investment to build the company; and three, share buyback.

As you have seen through what we have done over the last quarters, we have been, I think, totally aligned with this strategy in terms of investment in internal R&D. As David said, a 69% increase in R&D investments Q2 this year versus Q2 last year. As you've seen with the announcement of actually our third share buyback plan today, also being very aggressive there.

As you see, we have done a few deals in the last year in our external collaborations. We have not acquired any company at this stage. We see this, to your point, as how do we expand the potential of the company to deliver on its mission to make innovative medicine?

And on external front, I think there's always 2 filters that are important for us, is finding interesting assets and finding them at a price that we think we can create value for. As we've said and David confirmed today, our busy teams are extremely busy looking at a lot of things. But as you know, it's a bit the same as investors are looking for companies who invest. We need to look at a lot of things before we decide to go for something.

We won't be shy if we find great assets. There's a lot of assets that are very early. There's lot of assets that don't really fit the company's strategy. We'll keep looking. I think doing a large acquisition for the sake of large acquisition is not our strategy. What we want to do is to be the best nucleic acid company in the world. As we've said, we'll be very happy to go outside mRNA as long as we stay to the nucleic acid space. We'll be happy to do acquisition. If we find good assets, we'd be happy to do partnerships. An acquisition is not a goal in itself. So that's a bit how we think about outside investment, Matthew.

Operator

Our next question comes from Elizabeth Webster with Goldman Sachs.

Elizabeth Daniels Webster - *Goldman Sachs Group, Inc., Research Division - Associate*

This is Elizabeth on for Salveen. Congrats on the quarter. Could you walk us through the path to authorization for 1273.222 and just clarify exactly what the path is here. And then when could we see data from the trials you mentioned that are starting this month?

And then our second question is, if you had to think of levers for potential upside to the $21 billion in APAs, where might those come from? And could additional new orders come online?

Stephen Hoge - *Moderna, Inc. - President*

Thank you for the question. I'll take the first one, and I assume to pass to Arpa for the second. So first on the 222, this is a bivalent vaccine that is based on the BA.4, BA.5 variant, this is most -- I think the question is directed mostly to the FDA guidance and the focus, particularly in the United States, on authorization of that vaccine. We continue to work hard to pull together, both preclinical and manufacturing data and all of our underlying bivalent platform data, which includes 2 different Phase II/III studies that I referenced, the mRNA-1273.211 and mRNa-1273.214, both of which demonstrated superiority of the bivalent platform and the performance against Omicron variant of concern.

So the totality of that data, those 2 Phase II/III studies plus preclinical data and manufacturing data will form the submission, which is consistent with the published FDA guidance. FDA has also asked us, as you referenced, to run an additional study really to support future deployment because we do want to understand the performance of the 222 vaccine, if there's further variant evolution, for instance, in December or January. It has unfortunately happened every year in this pandemic. And we want to have samples that allows us to inform that sorts of decisions about deployment of the vaccine.

We expect to enroll that study really in August, but the data wouldn't be available for a few months because you would follow until approximately a month to get the boosted samples, collect them and then test them in the relevant assays. We do not, at this point, expect nor the FDA has suggested that, that data would be required prior to authorization. In fact, we will be authorizing, based on the prior clinical data for 211, 214, the preclinical data and manufacturing data. But we will have that -- those samples in hand.

Now as to the specific timing of when we would be able to share 222 data other than later in the fall, I don't think we have any other specific items today, except to emphasize again that it's really not required for the authorization based on recent FDA guidance. It really is to support future deployment decisions that are in the later part of winter.

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

And then I can take that second question on the $21 billion guidance. From an advanced purchase agreement perspective, we do believe the majority of the market demand is captured in this $21 billion. That being said, we continue to work with countries around the world on potential additional orders for our bivalent vaccines as many countries are continuing to assess their public health needs as well as their booster population recommendations and considering potential expansions to those populations. So we're feeling pretty good about the $21 billion, but we do continue to work with countries to see if and when there is additional demand for either the 214 or the 222 bivalent vaccine.

Operator

Our next question comes from Michael Yee with Jefferies.

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

A quick question in relates to the comments around getting the BA.4/5 222 authorized. Stephen, you had mentioned the pathway there. But I actually wanted to think a little bit forward. Do you envision that future variants and development vaccines would be able to be authorized quickly via just preclinical data such as like flu? Do you think that, that's where the path is going and that the FDA seems to be going along that route? That's the first question.

And then second question, just ironically you had made comments around monkeypox vaccine. And now WHO has made comments around global health emergency. So I didn't see any update there and wondering if that actually had made any progress.

Stephen Hoge - *Moderna, Inc. - President*

Sure. Thank you for the question, Michael. I'll try and take both. So first on the approach, I think you're right. We do believe that the flu model for authorization of strain settlements, strain updates every year will make sense in the future for COVID vaccines and boosters. And in that sense, the authorization of 222, if the FDA -- if that does happen with the FDA and other markets follow, it really becomes the first instance of that.

We are still going to have to file for a supplemental BLA instantiating that, pulling together from that framework. But we are actively working with regulators, not just in the U.S. but globally to try and establish that pathway. Because at the end of the day, in order for us to take full advantage of the platform and respond every year, it makes sense that we don't conduct clinical studies before authorization in the future.

We also think that the flu model and the performance of the platform globally, now in billions of people, really does start to demonstrate the potential for us to mature to more of an endemic approach that doesn't require a clinical study every time.

So that is our expectation and hope. We'll obviously engage with regulators over the fall and winter as we complete those filings and try and prepare for 2023 that might look just like that. And again, I think that 222 experience this fall really might just be that first instance of what becomes the new norm.

Now on monkeypox, we did initiate a research program. We are tracking that very closely. And obviously, given the recent public health announcements and increasing concern about availability of vaccine supply, we have been beginning to look at what it would take for us to use our platform to provide a monkeypox vaccine, both intervene in the current epidemic, but also to try and address long-term issues of supply in this public health threat.

We do not have any updates on those discussions. We will firm them up. Those will include, if appropriate, some regulatory consultations. And once we have clarity on whether we are moving to clinical development and what that path would be, we'll, of course, provide an update on it. But at this stage, it remains a preclinical program, but one that we're tracking very closely given the recent developments.

Operator

Next question comes from Gena Wang on Barclays.

Unidentified Analyst

This is [Sheldon] on for Gena. Congrats on the good quarter. We have two questions. One is on the current APA for 2022. Could you comment on how much -- how many doses for the COVAX contracts are still unallocated and how they were accounted for in the current $21 billion guidance? And could you also remind us on the current APA for 2023? And how should we think about the demand next year?

And a quick follow-up, another question on mRNA-1010 flu vaccine, the Phase III immunogenicity trial. How do you think about the expected data time line? Do you need to enroll also in the Northern Hemisphere?

Stephen Hoge - *Moderna, Inc. - President*

Maybe I'll take the last question first. And Arpa, do you want to take...

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

Yes. Sure. We'll take it in order. So just to reiterate, the $21 billion in advanced purchase agreement does not include any additional COVAX doses to be allocated. So that already reflects a lower demand that we're seeing from the COVAX countries. And we anticipate that for the remainder of the year, we'll see very few additional orders and/or demands from these countries.

In terms of 2023 orders, we have already signed deals with 5 countries that we've previously announced, the United Kingdom, Canada, Australia, Kuwait and Taiwan. We have also signed options with Canada, Switzerland, Taiwan as well. And we are actively having dialogue with countries around the world for additional orders in 2023. We will be able to provide additional guidance on what these advanced purchase orders look like later this year or early next year.

Stephen Hoge - *Moderna, Inc. - President*

Great. And then on the question of the flu Phase III study that's ongoing, so that is a Southern Hemisphere immunogenicity and safety study. As we said, we're moving -- that study is ongoing. We haven't characterized where we are. The -- we do not expect at this point that we would need to rotate that study into the Northern Hemisphere, so we'll be concluding that safety immunogenicity study enrolling in the Southern Hemisphere.

We do expect to run a Phase III efficacy study in the Northern Hemisphere in the later part of this year. And so we will be studying Northern Hemisphere comparators this year, but not the current ongoing Phase III, that is the safety immunogenicity study that we believe could support accelerated approval.

Unidentified Analyst

So just a follow-up, of the Southern Hemisphere immunogenicity data, so likely data will be available later in 2022.

Stephen Hoge - *Moderna, Inc. - President*

So we haven't specifically guided on when the data will be available. But generally, as you know, those safety immunogenicity studies after they enroll follow non-inferiority or superiority endpoints at day 29, so 1 month after [booster]. And so the data will follow shortly once we've completed enrollment. But ultimately, we will also want to follow up with safety data and consult with regulators about their expectations of what sort of follow-up data they would like to see. And so until we've had all of those consultations, we won't specifically guide on timing.

Operator

Our next question comes from Tyler Van Buren with Cowen.

Tara A. Bancroft - *Cowen and Company, LLC, Research Division - VP*

This is Tara on for Tyler. So I was hoping you could provide some comments on the 11% share gain that Pfizer was referring to since January 1 and where that might be coming from. Like is most of it coming from the adeno vaccine given the share that they have lost? And of course, I'd be interested to know where the Spikevax share changes are coming from as well.

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

Sure. I can take that question. In terms of the share, the shares that we reported today are looking at the cumulative share for Spikevax across just the third and fourth boosters, which is a difference compared to some of the data that Pfizer has shared and also looked at the major markets, the OECD markets that we play in. So as we think about the majority of where our source of business is coming from, we're seeing substantial market share holds and, in some cases, even some market share gains year-to-date. Again, focusing just on the booster population, which is where the vast majority of our current and future growth is coming from.

Operator

Our next question comes from Geoffrey Meacham with Bank of America.

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

On Slide 23, you guys gave sort of an illustrative example of kind of the longer-term opportunity for COVID. I want to just get, as you invest in '23 and beyond, not asking for guidance, but how do you think about what would be the tail of the endemic phase in terms of either volume or patients, et cetera?

And then a related question in terms of capital allocation, how do you guys think about investing in business? As I know, Stephane, the goal here is to further expand the reach of Moderna's technology in one of your slides. But how do you think about adding capabilities that are outside of that, that may be peripheral, but I wasn't sure how far you're willing to sort of steer a little bit away from the core mRNA.

Stephen Hoge - *Moderna, Inc. - President*

Okay. So I think maybe, Arpa, you and I will tag team on the first question and then come to Stephane on the M&A one.

So first maybe on the morbidity of the disease in that picture, we do believe that endemic human coronaviruses point a picture here would suggest there's going to be seasonal disease. There will unfortunately be breakthrough infection, some hospitalization, even some death. And that will happen indefinitely, particularly in those that are higher risk. The question, how we define that higher risk is 65 plus, 50 plus or is it 18 plus with high risk factors, or is it broadly, will really depend upon the evolution of the virus. It's hard to anticipate. But we do believe over time, this will become a seasonal market where boosting and elevating neutralizing protection to prevent breakthrough infections will happen annually in a large population, and they will benefit from it, just like they do for flu or they would for endemic human coronaviruses.

Arpa, I don't know if you want to comment on how that market evolves.

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

So the only comment I would add to that is we will continue to work closely with (inaudible) as well as governments around the world to see how their recommendations evolve for their populations in terms of the populations that are being covered and how often they're recommending booster. So we'll continue to work with them and over time see how the demand shapes up.

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

Thanks, guys. And on the capital allocation, as I've shared in the past, we are very interested by playing with information molecules, so nucleic acid. And so we're not only looking at mRNA to express human protein, as you know. We are also looking at mRNA through gene editing. As you know, we've already done some partnership there and we look forward to giving you some updates in the near future.

But then also in the gene therapy, we talked about RNA also being potential space of interest. So I think really depending at nucleic acid, I think as we've shared in the past, going to a small molecule or large molecule is not something that we think will build the best version of Moderna, again, taking a 3-, 5-, 10-year view of things. I think there's a lot of things we can do in terms of nucleic acid. And we like the ability to plug and play on to the platform across research, across development, across CMC. So there's really true benefit and synergies versus just getting the product for the sake of getting a product and driving more complexity into the company and getting into technologies that we see have little in common with nucleic acids.

Operator

Our last question comes from Ellie Merle with UBS.

Eliana Rachel Merle - *UBS Investment Bank, Research Division - Analyst*

Just as you think about the pipeline and capital allocation from here, can you help us think about just with the buybacks as well as further business development, how you're thinking about prioritization.

And then just a second question on monkeypox. Just I know that since you've announced that you have been looking at it preclinically and given the kind of public health emergency and broader vaccine needs, can you comment a bit your plans from here and any further plans for development?

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

So let me start on capital allocation, this is Stephane. As David illustrated on one of our slides that we have been using for a few quarters now, our priority #1 stays in investing in the business. We are really excited about the platform that we have.

As you know, in vaccine, given the vaccine modality has been derisked, we are willing to invest pretty aggressively. It's kind of remarkable that we already have 4 vaccines in Phase III right now. And as we shared on the last call, we have shown now 3x the ability to go from starting a clinical study in vaccine to starting a Phase III in around 12 months' time frame, which I think really speak about the platform of CMC capabilities and, of course, how we really build a very strong late-stage development team.

So the thing that's going to be interesting, of course, is the human proof-of-concept that we talked about coming later this year in cancer and in rare disease because if 1 of those 2 or both of those 2 were to work in terms of getting interesting clinical signal, you will most probably see us do what we did with vaccine, which is expand very quickly. As you know, one of the really good things about messenger RNA and how we build the company with a lot of robotics, a lot of digitalization is the ability to scale very quickly.

We already start in new applications like rare disease or cancer before we know if the technology is working. We kind of plan to start P&L with only a few programs. But if, let's say, we have a positive readout in PA, will you see us developing many more programs than what we have now in rare disease very quickly? The answer is yes. And we see something in oncology.

So investing in the business is priority #1. Priority #2 is really expanding the platform through partnership, licensing, M&A and then the excess cash that we will return to shareholders. And I think the announcement of a third buyback plan today with a new $3 billion authorization by the Board is a confirmation of the ability to return the capital if we cannot find good use in the company. Stephen, do you want to say about the monkeypox?

Stephen Hoge - *Moderna, Inc. - President*

Yes, yes. So look, I think conceptually, we're obviously very aware of the monkeypox concern and obviously very sensitive to recent announcements. And so what we are looking to do is understand if we were to develop that program, how would we move it? The purpose of moving it would be to move very quickly.

As Stephane just covered, our platform is pretty well established. And our ability to rapidly scale is -- has been demonstrated. And if we were to go after a monkeypox clinical development program, it would be to very quickly progress towards an approvable set of endpoints in a clinical study. And in that sense, we need to engage with regulators and other consultations to determine what that path would be. It's not primary or principal interest for us to just advance the program and demonstrate in Phase I clinical immunogenicity, we would really be doing it to try and help generate a public health countermeasure.

And so those conversations, we will start and we'll engage with them. We obviously also recognize. There are other even larger public health threats right now. COVID remains a larger public health threat, and many regulators are totally focused on addressing the updated booster work for this fall. And so we're respectful of that. But we will engage in those conversations. And once we have clarity on whether or not we will go forward, given what we think those endpoints will be, we'll obviously provide it. But at this point, it's premature to say more because we have not clarified those endpoints and therefore have not made our own decision about whether we will move the preclinical program into clinical development at this stage.

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

Well, thank you so much, everybody, for joining the call today for your questions. We look forward to speaking to many of you and look forward to welcoming you at our R&D Day early September. Have a great day. Thank you.

Operator

Ladies and gentlemen, this does conclude today's presentation. You may now disconnect, and have a wonderful day.