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PRESENTATION

Operator

Good morning. My name is Kevin, and welcome to Moderna's First 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 first quarter 2022 financial results and business updates. 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; and Paul Burton, 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.

I will now turn the call over to Stephane.

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

Thank you, Lavina. Good morning or good afternoon, everyone. Welcome to our Q1 2022 conference call. Today, I will start by a quick business review of the quarter before Paul walks you through an update on Spikevax real-world evidence, and then Stephen reviews our clinical programs. David will then present the key financials, and I will then come back to conclude before we take your questions.

I'm happy to share that the team delivered strong financial results this quarter. Revenues of $6.1 billion, GAAP net income of $3.7 billion and GAAP diluted EPS of $8.58. We ended Q1 with a cash balance of $19.3 billion. For our share buyback program, we continue to retire shares in Q1 like we already did in Q4. David will share some numbers on share count in a few minutes.

For 2022, we are reiterating $21 billion in signed advanced purchase agreements. We have previously shared market share increases seen in the OECD countries with Spikevax when supply was no longer limited and when real-world publications highlighted differentiating data amongst the market vaccine. I'm happy to share that our market share has increased or still consistent across OECD countries.

While a subset of our team is focused on delivering on the $21 billion signed APAs for fiscal year 2022, another subset of our team is focused on preparing the next wave of product launches. With our flu vaccine candidate, mRNA-1010, plans to start a Phase III study in Q2 in the Southern Hemisphere, Moderna will have very soon 4 vaccine candidates in Phase III. An Omicron containing bivalent COVID booster, a flu booster, an RSV booster and the CMV vaccine.

Starting with our Omicron containing bivalent COVID booster, mRNA-1273.214, we could see up to 3 respiratory vaccine launches from the fall of 2022 over the next 2 to 3 years. We believe each of these 4 vaccine candidates in Phase III could have multibillion-dollar annual peak sales. And because they all use the exact same mRNA technology as our approved vaccine, Spikevax, we believe this pro-vaccine candidate in late-stage clinical trials have a high probability of success.

In addition to our 4 late-stage vaccine, we continue to expand the applications of mRNA technology beyond vaccines. We should have important proof-of-concept data in patients in 2 of our therapeutic modalities later this year. Propionic acidemia and methylmalonic acidemia in our rare genetic business portfolio, and the personalized cancer vaccine.

Slide 7 shows the continued growth of Moderna. We now have 46 development programs in the pipeline. The organization has continued to grow to 3,200 team members.

With that, let me hand it over to Paul to review real-world evidence studies of our COVID booster. Paul?

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

Thank you, Stephane, and hello, everyone. While there continues to be many studies posted and published on our mRNA vaccine, I would like to highlight some data today on vaccine boosting. But first, it's important to understand why booster vaccines are so critical as we transition through the COVID-19 pandemic and the understanding that we need to have about the evolution of the SARS-CoV-2 virus.

On Slide 9, we can see the change in COVID-19 cases over time, with the massive rise we observed due to Omicron in the last weeks of 2021 in the early part of 2022. The Omicron wave was caused by BA.1. And while that was certainly the dominant version of SARS-CoV-2 at that time, remarkably, BA.1 is now almost extinct here in the United States and around the world having been replaced by new subvariants. This continues to demonstrate the remarkable evolutionary capacity of this virus.

BA.2 is now the dominant strain in the in the United States, with another subvariant of that BA.2.12.1 increasing rapidly, showing enhanced transmissibility. While BA.2 is dominant today, that increased transmissibility and infectivity of BA.2.12.1 is likely going to ensure it will be the dominant circulating strain very soon as we are seeing in New York and in the Northeast of the United States. Other new subvariants BA.4, BA.5, seen in South Africa, have also been detected in the United States, and we will need to carefully monitor their growth trajectories and pathogenicity.

The slowing of booster uptake now means there will be individuals who are undervaccinated and underprotected as we move into late spring and summer when we thought we would have declining case counts and balance, which could now be impacted by BA.2.12.1, BA.4 or BA.5. The speed and breadth of evolution of this virus that we see so clearly again today underpins our prediction for the global need for a varied adapted booster campaign this coming fall.

The good news is that a booster of vaccine protects against both BA.1 and BA.2. This is seen clearly when we look at data from the United Kingdom Health Security Agency. This graph looks at vaccine effectiveness against symptomatic disease for people who received the Moderna, Pfizer or AstraZeneca vaccine for their primary vaccination on the left. You can see that against both BA.1, Omicron and BA.2, vaccine effectiveness wanes over time. But a booster dose of either the Pfizer or Moderna mRNA vaccines increases vaccine effectiveness and protection, as you can see on the right.

These 2 vaccines are combined together in this analysis. But again, even in this setting, there's gradual waning of vaccine effectiveness over time following boosting. This waning of vaccine effectiveness begs the question, will a second booster dose provide clinical utility and help to restore vaccine effectiveness and provide protection against COVID-19?

While there are several examples of studies showing the high clinical effectiveness of additional boosting with the Moderna vaccine, on Slide 11, I want to highlight the results of a recent study from Ontario that looked at exactly this question and measured the effectiveness between a first and second booster vaccine dose in a high-risk population, those people living in long-term care facilities.

A key finding from this study, which was conducted in over 55,000 individuals, was that indeed, a second boost of vaccination showed increased vaccine effectiveness against Omicron infections, symptomatic disease, and importantly, against severe outcomes in this high-risk setting. In fact, an increase in vaccine effectiveness was seen at 7 days from the second booster vaccination and continued to increase in effectiveness over time.

Turning now to Slide 12. I would like to provide a perspective on who might gain particular benefit from annual vaccine boosting. There are many health, age-related and environmental occupational risk factors that lead to populations being at higher risk for COVID-19. First, age greater than 50 years. We know that hospitalization and mortality rates begin to increase steeply for those with COVID-19 who are over the age of 50.

And then turning to people over the age of 18 that have other health risk factors, such as people with kidney disease, cancer, autoimmune disease and HIV patients, other health factors that either result in immunocompromise or place people at higher physiological risk for severe disease, if indeed, they are infected with SARS-CoV-2.

Finally, environmental or occupational risk factors, such as health care workers, first responders, those in high-density housing or living conditions such as college students, military personnel or the incarcerated. We believe it is people in these broad categories who could benefit most from annual boosting for COVID-19.

And so in summary, we've seen as we continue to anticipate SARS-CoV-2 to keep evolving rapidly with multiple new variants and recombinant variants circulating globally. Real-world evidence demonstrates the effectiveness of a booster shot, a third dose of mRNA-1273 against evolving variants of concern. And an additional booster, a fourth dose of mRNA-1273 shows incremental vaccine effectiveness when compared to a third dose against infection, symptomatic infection and severe disease in a high-risk population.

We believe people are at high risk due to health, age and environmental or occupational risk factors. And we believe that when taken together with the viral epidemiology and waning of protection, there is an important need for a variant-adapted booster vaccine and for boosting of populations this coming fall.

With that, I'll now turn it over to Stephen to take you through the progress in our clinical development pipeline. Stephen?

Stephen Hoge - *Moderna, Inc. - President*

Thanks, Paul. Good morning and good afternoon, everyone. Paul just shared with you the effectiveness of our booster mRNA-1273 against Omicron in the real-world setting. But on Slide 15, I'd like to pivot to our strategic rationale for why we think a seasonal booster will be necessary.

So first, we think neutralizing titers will wane similar to the endemic human coronaviruses. And that decline in neutralizing titers will increase their risk of breakthrough infection and hospitalization for those at higher risk, particularly as Paul just described, older adults or those with medical -- immunocompromised. The emergence of new variants of concern like the BA.4, .5 subvariants could accelerate the impact of that waning and

broaden the risk of breakthrough across the population. So with that, we do believe a booster will be needed in the fall, and we're working hard to make improvements to our available boosters.

The desired features for a Northern Hemisphere fall-winter booster, we think will be that it improves the durability of protective neutralizing antibodies against Omicron and its subvariants beyond 6 months, i.e., the full Northern Hemisphere fall and winter infection season. We'd like to retain high and durable protection against Deltas and ancestral strains, and we'd like to broaden cross-protective immunity to increase the potential for protection against new emerging variants or subvariants that might happen over the coming months.

So on Slide 16, I'd like to summarize our work in developing that improved booster. Our primary focus, as you know, has been on developing a bivalent vaccine, and we have taken 3 bivalents into clinical trials. The first mRNA-1273.211 includes 9 of the common mutations and was based on a combination of our prototype wild-type vaccine and Beta. The mRNA-1273.213 bivalent included 11 mutations based on what had emerged from Beta and Delta. And our mRNA-1273.214 booster includes 32 mutations, also now based on the wild-type prototype vaccine and the combination with the Omicron original variant of concern.

Our latest bivalent, mRNA-1273.214 that includes those 32 mutations that have emerged remains our lead candidate for the fall Northern Hemisphere campaign. The objective of that booster will be to demonstrate superior immunogenicity against variants of concern when it compares to our approved current prototype booster or mRNA-1273 at 50 micrograms. And of course, we want to maintain noninferiority against ancestral strains in case they reemerge.

Now on Slide 17, I'll summarize the ongoing clinical development work across that portfolio of bivalent boosters. I'll remind you that mRNA-1273 has been authorized or approved in many markets as a third and even a fourth booster. The data for the first bivalent, mRNA 211 has already demonstrated superiority against all variants of concerns tested, including Omicron and Delta, and I'll cover that data in just a moment. But our lead candidate remains, as I said a moment ago, our mRNA-1273.214, which is being evaluated in 2 separate studies, a Phase II/III in the United States and a Phase III P305 study in United Kingdom. Again, both of those are being conducted at a booster dose of 50 micrograms.

Now on Slide 18, just quickly to update you on the data we have from the 211 first bivalent. Not surprisingly, the safety and reactogenicity profile of the bivalent boosters is consistent with what we saw with mRNA-1273. As you'll see on the chart, both solicited adversary local reactions and systemic reactions are broadly consistent in both frequency and severity. And the frequency and types of unsolicited adverse events were also comparable between the groups with no serious adverse events in the bivalent vaccine group up to 28 days after the booster dose.

Moving to Slide 19. We have some of the neutralizing antibody data from that study, evaluating again, our mRNA-1273.211 bivalent and comparing that with an approved or authorized mRNA-1273 booster. Looking at neutralizing titers and GMTs, both immediately pre-booster at 1 month or day 29 at 6 months on day 181, across the 3 variants of concern which we tested, higher neutralizing titers were seen for day 29 and day 181 across all the variants of concern with the bivalent booster.

On Slide 20, we represent that as a ratio and comparing the performance of the bivalent booster to mRNA-1273 at 1 month and 6 months, and superiority was met for the ancestral and all variants of concern at different time points, as you'll note here. The clinical endpoint for superiority was defined as a geometric mean titer ratio, or GMR, where the lower bound excluded -- the lower bound of the 95% confidence interval excluding one.

And as you'll note, at day 29, a GMR for the ancestral SARS-CoV-2 virus was 1.28; Beta was 1.3; Delta was 1.75; and importantly, Omicron was as high as 2.2. And the 95% confidence interval for Omicron, the lower bound was 1.74, again, demonstrating strong trend towards superiority in this data. Excitingly, at day 181 or 6 months, that superiority was also met for the ancestral virus, Beta and the Omicron variant, which is important because the primary goal we have here is to improve the durability of protection by increasing those titers.

So on Slide 21, in conclusion, the safety and reactogenicity profile of the 50-microgram bivalent 211 booster was comparable to the 50-microgram of the authorizer-approved 1273 booster. And we believe that the superiority already demonstrated by the bivalent platform in 211 bodes well for our overall strategy. We continue to believe that bivalent boosters will ensure the broadest immunity across the evolutionary certainty of SARS-CoV-2

and maintain current protection while expanding the breadth and durability of neutralizing antibodies, including, as I just demonstrated a moment ago with 211, out to 6 months. We anticipate the 1 month or day 29 data from our Omicron containing bivalent mRNA-1273.214 in June of 2022.

Now turning to the rest of our respiratory vaccine pipeline on Slide 23. We announced positive Phase II data from our flu vaccine, mRNA-1010 at our Vaccines Day event. mRNA-1010 is our -- is part of our speed-to-market approach. We plan to start a Phase III immunogenicity study in the second quarter of this year and a Phase III efficacy trial later this year with mRNA-1010. As part of our flu vaccine strategy, we are also advancing in parallel, vaccine candidates that contain both HA antigens and NA antigens. We started a Phase I/II trial of mRNA-1020 and mRNA-1030 last month.

Our RSV vaccine, mRNA-1345, a Phase III trial in older adults is ongoing, and we are enrolling participants worldwide. We also have an ongoing pediatric RSV trial enrolling as well. In combinations, we plan to start a Phase I trial for both our COVID plus flu and our COVID flu RSV vaccines this year. Our Phase I trial for the hMPV/PIV3 combination vaccine is also now fully enrolled. And our RSV and HMPV combo and our endemic human coronavirus vaccine combo are in preclinical.

Before moving from respiratory vaccines, I wanted to take a step back and reflect on the incredible progress over the past 2 years. We have or will have progressed 3 candidates into pivotal Phase III studies within 1 year of an IND being opened. This speed is made possible by our mRNA platform. And we believe our COVID vaccine success has derisked our vaccine pipeline, and we can now move quickly into our RSV and flu pivotal studies. Importantly, in RSV and flu, we are looking at seasonal endpoints or immunogenicity endpoints, which we believe can be -- can allow us to progress faster through Phase III towards its readouts and ultimately to commercialization.

Now turning to the rest of our pipeline. We have an ongoing Phase III study for our CMV vaccine, mRNA-1647, which is enrolling well and is now enrolling participants globally. Our EBV vaccine to prevent infectious mononucleosis is in Phase I, and our EBV vaccine to prevent long-term sequela such as multiple sclerosis is in preclinical studies. Our HIV vaccines are in Phase I clinical trials with our partners. And the recently announced HSV and VZV vaccines are in preclinical studies.

Within public health vaccines, our Zika vaccine continues to enroll in Phase II. And we are pleased to update that our Nipah virus vaccine, IND, was opened, and we look forward to starting that trial soon with our partner.

Now moving to our therapeutic pipeline on Slide 26. Within oncology, our personalized cancer vaccine is ongoing in a Phase I study and a Phase II study. And we expect the first look at the data from our Phase II study, which is evaluating personalized cancer vaccine plus KEYTRUDA versus KEYTRUDA alone, in the fourth quarter of this year. We have 4 other candidates in Phase I or preclinical stages across oncology.

In cardiovascular and autoimmune, we have 2 candidates in each area in clinical trials or in the preclinical stage. And within rare diseases, our propionic acidemia program, or PA program for short, which I will give more detail on the next slide, is ongoing in a Phase I/II study. Our MMA program is also ongoing in the Phase I/II study. And our GSD1a program has an open IND and we look forward to enrolling the first participants in that study. We have 3 other candidates in preclinical and rare disease as well.

Now before I hand it off to David, on Slide 27, I wanted to provide a bit more color on our Phase I/II study in propionic acidemia. As a reminder, PA is a rare metabolic disorder that is characterized by a deficiency of propionyl-CoA carboxylase, an enzyme that's involved in the breakdown of several of the building blocks of proteins called amino acids. As a result, a deficiency in that enzyme, harmful intermediate compounds can build up to toxic levels in the body. This can lead to serious health problems, including recurrent episodes of life-threatening metabolic decompensation events.

Our therapy for PA encodes for 2 of those proteins that form the deficient enzyme, PCCA and PCCB, and has 1 mRNA for each in the drug. The Phase I/II study is an adaptive trial design, enrolling participants greater than 1 years of age in the United States, United Kingdom and Canada. Participants received 1 dose of mRNA-3927 every 2 or every 3 weeks for up to 10 doses in that study.

The first cohort is fully enrolled, and we are now enrolling patients in the additional cohorts. Five patients have now completed the initial 10-dose course of the study and became eligible for continuing dosing in the open-label extension. And all 5 of those patients have elected to participate in the OLE. A total of 75 doses have now been administered across Phase I/II and the OLE study.

Now the study is focused on evaluating safety and PK/PD. It is also looking at clinical events, those that are most important, including the metabolic decompensation events I mentioned previously. And of course, we are also evaluating potential biomarkers in the study. We look forward to enrolling more patients and sharing the data this year.

And with that, I'd like to turn this over to our financial review from David.

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

Okay. Thank you, Stephen. We're providing today the analysis of actual 2022 first quarter results, along with a view of key drivers of financial performance going forward. Overall, we had a good start to 2022, and I'm very pleased with our operational and commercial performance.

Turning now to Slide 29, starting with an overview of our sales performance. Total product sales in the first quarter of 2022 were $5.9 billion. This compares to product sales of $1.7 billion in the first quarter of 2021. The total sales growth is driven by the fact that we were in an earlier stage of our manufacturing ramp-up in Q1 of last year, with our U.S.-based manufacturing lines roughly 3 months ahead of our international manufacturing capabilities. This also explains the different geographic sales mix. In the first quarter of 2022, sales outside the U.S. were $5 billion, and sales to the U.S. government were $0.9 billion. The majority of sales in Q1 of last year were to the U.S. government.

Turning to Slide 30 to go into more detail of our Q1 results. Total revenue was $6.1 billion in the first quarter of 2022 compared to $1.9 billion in Q1 of last year. The increase of total revenue was driven by the sale of our COVID-19 vaccine. Cost of sales was $1 billion or 17% of the company's product sales in the first quarter. Cost of sales in percent of sales in Q1 of last year was 11% on a reported basis and 22% on adjusted for prelaunch inventory costs, which were expensed in 2020.

Compared to the prior year adjusted 22%, we are benefiting this quarter from an increased average selling price driven by customer mix, favorable impacts from the scale-up of our manufacturing processes, partially offset by higher write-downs for excess and obsolescence inventory and a current period expense related to future purchase commitments.

Research and development expenses were $554 million in the first quarter of 2022 compared to $401 million in the same period in 2021. The increasing R&D spend continues to be driven by clinical trial expenses for our expanding and maturing development portfolio.

Selling, general and administrative expenses were $268 million for Q1 2022 compared to $77 million for the same period in 2021. 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. Our Q1 2022 results also include the initial upfront endowment of $50 million for the newly established Moderna Foundation.

Provision for income taxes was $572 million in the first quarter of 2022 compared to $39 million in the prior year period. Our effective tax rate for the first quarter was 14%. Let me remind you of the fact that we had 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.

We recorded after-tax net income of $3.7 billion in Q1 compared to $1.2 billion in the prior year. Diluted earnings per share in Q1 2022 were $8.58. As a final point on the quarter and beyond, we currently do not have any commercial activities or R&D activities in the Ukraine or Russia.

Turning to cash and cash deposits on Slide 31. We ended Q1 2022 with cash and investments of $19.3 billion compared to $17.6 billion at the end of 2021. The increase is driven by our commercial activities. The balance of cash deposits for future product supply was $5.3 billion compared to $6 billion at the end of 2021. The reduction quarter-over-quarter is driven by product deliveries against customer deposits.

Now turning to Slide 32. 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. For R&D, we continue to forecast to spend in the range of $2.5 billion to $3 billion in order to advance and accelerate our pipeline, both for existing and new programs.

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. We completed our initial $1 billion share buyback program in January and announced a new share buyback program of $3 billion in February. Across these 2 authorizations, we repurchased a total of 3.8 million shares for $0.6 billion during the first quarter.

The next slide shows a progression of our share count since we initiated our share repurchase program. As a reminder, we received board approval for our initial $1 billion share repurchase program in August 2021 and began repurchasing shares in the fourth quarter of 2021. Our quarter-end basic shares outstanding declined from 405 million at the end of September 2021 to 400 million at the end of March 2022.

We repurchased 7 million shares, more than offsetting 2 million shares of common stock issued in connection with equity compensation over this period. Our diluted weighted average shares outstanding also declined from 434 million in the third quarter of 2021 to 426 million in the first quarter of 2022, primarily as a result of the share repurchase activity.

Now let's turn to 2022 financial framework on Page 34. We have signed advanced purchase agreements for expected delivery in 2022 in the amount of approximately $21 billion. There's a potential downside to this number from timing of COVAX deliveries if COVAX is unable to confirm demand aligned to their contracted volume in the 2022 calendar year. There is also an upside to this number from potential additional contracts for the fall booster dose, including for the U.S. market.

In 2022, we believe that the SARS-CoV-2 virus will evolve into an endemic phase with a more seasonal sales pattern. As a result, we continue to expect the timing of sales to be larger in the second half of 2022 than in the first half.

Our total cost of sales includes the cost of goods manufactured, third-party royalties as well as logistics and warehousing costs. We continue to expect cost of sales as a percent of product sales to increase compared to prior year, driven by both a decrease in our average selling price and a forecasted increase in manufacturing cost. The year-on-year decrease in average selling price is due to the higher share of COVAX APAs for delivery this year compared to last year.

As the COVID-19 pandemic evolves into an endemic phase, we forecast our manufacturing unit costs to increase. This is driven by a move to smaller dose presentations and the cost for adjusting our production and supply chain infrastructure, including future purchase commitments. We continue to expect our full year 2022 reported cost of sales in the low to mid-20% range, which incorporates all the expected adjustments that we've identified for the 2022 calendar year. The cost of sales for Spikevax beyond 2022 will be further impacted by geographic customer mix, the pricing effects of the private market as it develops as well as our initiatives to optimize and improve efficiency.

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 scale up of the company. Based on current tax laws, we continue to expect our 2022 tax rate to be in the mid-teens as a result of the benefits from the foreign-derived intangible income, driven by our international business mix and stock-based compensation deduction. 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.

As this is the last earnings call for me as CFO of Moderna, I would like to take the opportunity to welcome Jorge Gomez, who's well qualified to lead Moderna in the next stage of its development. I would also like to recognize my own team and my colleagues for our success in ramping up a global commercial company and contributing to taming the pandemic. I have great confidence in the company's ability to fully realize the vast potential of its mRNA technology platform against the many remaining unmet medical needs.

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

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

Thank you, David, for that review of the quarter and those kind of words. More importantly, I would like to thank you for agreeing to come out of retirement in the spring of 2020 to help us scale Moderna at an unprecedented speed from an early-stage development U.S.-centric company to a commercial, global company. I am very grateful for you agreeing to come out of retirement to help us. Your work to get us to this point was crucial. You built a strong team and robust business processes. Thank you for also agreeing to stay on as a consultant as we transition to your successor. And so I want to wish you and your wife well in the next phase of your life.

As many of you know, we announced that Jorge Gomez will join us as Chief Financial Officer, effective next Monday, May 9. Jorge brings with him experience in the capacity of CFO for global health care organizations, which are Dentsply and Cardinal health. Jorge has the same kind of high-quality finance trading as David as a General Motor finance alumni. He has a broad set of international experiences in addition to having been CFO of publicly-traded companies.

I would also like to welcome Arpa Garay, who is joining us from Merck at the end of this month as our Chief Commercial Officer. She was a member of Merck Executive Committee where she most recently served as Head of Marketing. Arpa also has a very impressive background and multiple experiences in both sales and marketing. I look forward to partnering with these 2 leaders to continue to scale rapidly Moderna.

Before moving to Q&A, I would like to review with you our 2022 priorities. Priority number one, to execute on the $21 billion of signed APAs and to prepare for a successful fall 2022 booster season.

Priority number two, to execute on our 4 Phase III vaccine programs, an Omicron COVID-19 bivalent booster, flu booster, RSV booster and CMV prime series vaccine, which could lead to 3 respiratory commercial launches over the next 2 to 3 years.

Priority number three, to expand beyond infectious disease vaccine into therapeutics and share proof-of-concept with for PA, MMA and PCV programs.

Priority number four, to bring forward more M&A candidates into clinical development.

And last but not least, priority number five, to continue to expand our mRNA platform, so the possibility of mRNA impact to patients continues to increase over time.

I also wanted to remind people of our upcoming events this year, (inaudible) in just 2 weeks on May 17. We'll also host our typical annual R&D Day in September and first ESG Day in November.

While we have had a profound impact on humanity over the last 2 years, we believe that what is ahead of us to help protect and treat hundreds of millions of people is even more exciting. We'll continue to execute on our mission, and we thank you for your support. This is just the beginning.

Operator, we'll be happy to take questions now.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Salveen Richter with Goldman Sachs.

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

And David, it's been a pleasure working with you. Two questions for me. One is for COVID, based on what's known right now, what regimen as you think about dosing in candidate do you have the most confidence on for annual boosting as you look to in 2023 and beyond?

And then secondly, just given your balance sheet and the -- as you look to kind of entering an endemic phase here, how are you thinking about later stage BD and M&A to bolster the revenue line?

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Salveen, it's Stephen. So first, on the COVID booster and what we perceive. As of today, subject to data and obviously collaborating with regulators, we are, as I said, most excited about our bivalent vaccine platform and including Omicron as the now dominant variant and family of subvariants that are infecting people today. Our objective, just like with our bivalent 211 booster data that I presented today, is to provide at least 6 months of protection from that.

And because we think this will be a seasonal vaccine, it will be very similar to what people are used to from a food perspective. Meaning in the Northern Hemisphere, you get boosted in the October time horizon, and that would cover you well through the early part of spring when transmission will subside. And so provided that we are able to provide that duration of protection as we've demonstrated already with the 211, we actually think then that means a seasonal annual booster in the fall that would cover people for the year. And as I said, we think it will be the bivalent Omicron containing booster for this year.

For 2023 plus, we would expect to continue to update the bivalent platform to reflect the then dominant or then at-risk circulating strains of the variant. So it maybe Omicron this year. It may be Omicron again next year or it may be something new.

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

Thanks, Stephen. It's Salveen, it's Stephane. So as you know, in term of capital allocation, our priority #1 is to invest in the business. We believe we have this really unique platform that is very different from typical pharma companies or biotech companies where we have an ability to scale very quickly. As we discussed today, we are actively preparing the pivotal studies and the launch of 4 programs in Phase III, as we discussed. As you know, there's a lot of program in Phase II. And I think there's around 30 vaccines in development today.

And Stephen has showed you today that we believe we have built for our platform and all our investment in digital and a great team, we have the ability in around 12 months to go from opening an IND in vaccine to starting the Phase III. So I think where the pipeline is and where it's going to be 12 months, 24 months from now, that is really exciting.

And then there's therapeutics. We always get a question around COVID-19 for obvious reason. But as we've said in our remarks, this year will be very exciting around therapeutics. We have 2 rare genetic disease programs that are well recruiting, as Stephen described, for which we are eager when we have it, to share data with you. And assuming this is positive, we will do more in rare genetic disease.

As you recall, because you've been following the company for a long time, we started with a few infectious vaccines and as we got more confirmation that the technology was working in human and more recently, more capital, we had a very unprecedented acceleration of our infectious disease vaccine. Well, we plan to do the same in rare genetic disease if we get positive clinical data and in this personal cancer vaccine. And as you know, they are -- as Stephen said, more cancer programs, autoimmune programs. And also quite exciting to work with our partner, Vertex, towards getting, following the application, the CF mRNA candidate into the clinic.

In term of M&A, I can tell you, our teams have never been as busy. They are looking at a lot of opportunities literally across the world, across therapeutic area, but also technologies. And so we will not be shy to invest, to expand the platform, have [full] technology, full products, and that's really where we are in term of M&A. So more to come when things get finalized and signed.

And as you know, the third bucket of our priority is in terms of balance sheet, is returning shareholders to capital via share buyback. And so this, as David said, we'll continue to buy back share at attractive prices. And we'll continue to have a dialogue with the Board as to what should we do after the current plan, if needed. But now, we're all focused on executing the current plan. Thank you.

Operator

Our next question comes from Matthew Harrison with Morgan Stanley.

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

Great. I guess 2 for me. So first, David, could you just comment a little bit more on the upside and downside levers to COVID revenues this year? And in particular, what would be the features that would not allow COVAX to accept the deliveries? Or what should we be looking out for to understand that?

And then secondly, just on flu, could you maybe give some updated comments on where you are in terms of regulatory discussions? It sounds like it's not clear yet whether or not you're going to need a full efficacy study for approval. And so I'm just wondering where those discussions are and when you think you'll be ready to give people a clearer picture on what the outlook is for the flu program.

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

Sure. So on the first one, in terms of the outlook for sales in 2022, I think the most important point is COVAX had an option for additional doses in 2022, which they chose not to exercise. So that's impacted the outlook. We formally were reporting options that could be taken up. That's been taken off the table as they didn't exercise.

And what we see is, in our plans in the $21 billion, there continue to be some volume for COVAX. They are actually the consolidator of demand from the countries. So what they need to do is get the confirmed requirements from each country and then that becomes a confirmed order to the company. And notwithstanding having contracts, there's still that process they have to go through. So that's why we want to flag there's some level of uncertainty associated with the timing of that demand that we're reflecting in the APAs.

And then, of course, we have, as we've said before, a number of negotiations and discussions going on with other countries around the world as we look forward to the fall season and look forward to the variant booster offerings that are making their way through the approval process. So likewise, that presents some potential for additional sales that are not presently in the APA count for this year.

Stephen Hoge - *Moderna, Inc. - President*

Thanks. This is Stephen, Matthew. So on the question of flu and where we are, we have been consulting with regulatory agencies globally, as you might imagine, around a path forward for our mRNA-1010 program as there are issued guidance around accelerated approval that are still open. At the end of the day, we still believe that there's a potential path towards an accelerated approval at least in some markets with our mRNA-1010 program using a safety and immunogenicity endpoint as has been previously discussed.

At the end of the day, that will be a review matter, and we'll have to generate that data and have conversations on the back of that data with regulators as a path forward. But even if we do move forward with accelerated approval, which is the study that we're starting, the Q2 Phase III study that we're talking about starting this quarter. Even if we do move forward on the back of that, we will have an obligation even under accelerated approval to demonstrate efficacy at some point in a follow-on study to move from accelerated to full approval.

And so because we're certain of that need at some point, we are also planning to start a Phase III efficacy study, which will then be conducted perhaps in the Northern Hemisphere winter, this coming fall. And we also announced data plans for that.

And what that would do is, we would hope, we'd find a path forward for both the accelerated approval, but also rapidly being able to move that to a full approval on the back of that efficacy result. Now for some reason, the accelerated approval is not available in some markets or all markets, we would instead go directly to full approval with a very short latency given the timing of those 2 studies.

Operator

Our next question comes from Gena Wang with Barclays.

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

Congrats on the strong quarter. And David, we will miss you. I have a few questions regarding the revenues. David, you mentioned that second half this year will be higher than the first half. Since first quarter, we already delivered $5.9 billion revenues. Should we expect less than $4.5 billion for the second quarter this year?

And then my second question is regarding the ex-U.S. $5 billion revenue. What is the breakdown between you and the rest of the world?

And the third question is regarding the prices for U.S., EU and the rest of the world. And where do you see these prices change for the remaining of 2022 and also 2023?

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

Okay. Good. So I'll try to cover them all. And if I miss one, come back to it. So in terms of -- first of all, maybe I'll start at the end on pricing. We previously disclosed the ranges of pricing that we had in the contracts last year. And what you see is that pricing has continued as we contracted for 2021. So really, no change on the price across the various customers. It's really net prices being impacted, as I mentioned, by the mix of customers where we have our COVAX sales at the very lowest price offer. Whereas the other countries, the developed countries, we have varying higher prices.

So those continue. We haven't commented on pricing for beyond 2022. But certainly, I think it's fair to assume that, to the extent that the market moves to a private market, typically, you see higher prices and driving markets based on the needs of the market as opposed to when you're addressing the government-acquired product for -- in this pandemic context. So that's one.

Secondly, in terms of the 2022 outlook, I think you got it right. So basically, first of all, I think it would be a mistake for us to move into quarter-by-quarter accounting of where we see the demand given the variability of this pandemic. But what we see with the $21 billion of signed APAs, we mentioned last quarter and it's the same this quarter, that $21 billion we think will be somewhat higher second half sales than first half. And as you correctly pointed out, the math would then point to the second quarter being likely the lowest that we'll see throughout this year. So I think your thinking on that is right.

And sorry, the third point was?

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

Third point -- that's very helpful. The third question is ex-U.S. $5 billion revenue, what is the breakdown between Europe and the rest of the world?

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

Yes. So we had -- it was a pretty broad spread. I don't have top-of-mind with specific quantities by country or region, but it was a pretty a broad spread of demand if you look across the world in the first quarter.

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

Yes. And maybe just to add, Gena, it's Stephane. On the pricing, as David said, has moved into pandemic. As we've been saying, we have to discuss with payers as part of kind of health economics and value of products as it's done for every pharmaceutical product, especially in the U.S. And as you might be aware, CMS has already communicated that for fiscal year 2023, which starts in October 2022, the reimbursement for COVID-19 vaccine is going to be $60. Thank you.

Operator

Our next question comes from Michael Yee with Jefferies.

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

I have to ask the last question to David before he gets to go back and then a question for Stephen on the pipeline. I'm going back to the question around the guidance. Can you maybe help us quantify the exposure to COVAX? There was an article I guess talking about some of that recently in the press. And I think that's part of what your APA commentary out today is, I'm sure. Are you saying that, that's partly in the $21 billion, but then offset by potential U.S.A. orders that could come later this year? So maybe you could just talk about that dynamic a bit?

And then a question for Stephen is, again, definitely excited about propionic acidemia. Can you just rightsize your expectations because it's 5 patients but at the lowest dose? So is that a therapeutic dose you would expect to see biomarker changes? Maybe just talk a little bit about that.

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

Sure. So yes, so I'm not sure I have too much to add in terms of the color as to the outlook for the balance of the year. Certainly, again, the $21 billion, we don't, right now, have included any contracts as a result of additional U.S. business, which we think is quite likely we certainly believe there's a recognition of the need for boosters in the U.S., and the dialogue is quite active. That's also true around the world with our customers in other countries and regions.

And then we wanted to be clear that in the case of COVAX, which is as we've said before, the lowest priced business in the portfolio, but we have confirmed contracts there in place. And we wanted to flag that they are, as I said, a consolidator of underlying demand. And they continue to work through in those developing markets what is exactly that demand picture and what is the timing of it and the ability of those countries to absorb the product that they're receiving. So we want to flag that.

Quite frankly, if you ask me, should this be an issue of big concern in terms of the total outlook, I would tell you I would put it as quite modest. But we're trying to give some sense as to the range of outcomes in terms of this information.

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Michael. So look, you point to the most important things, I'll say, which is this [enrollment remains] a small number of patients. It's a rare disease. And as you said, we're looking now in Cohort 1 and Cohort 2 at our lowest dose levels, and we're continuing to enroll. And I would expect, as is appropriate for a Phase I study where we are doing dose finding, Phase I/II, that we will continue to enroll and explore a range of doses, including potentially higher doses in a Cohort 3.

Now that said, we will have a body of data building. As we said, we've got 5 participants who moved into the open-label extension. One has already -- at least one has already been approaching approximately a year on drug, a total of 75 doses. And so as you look -- as you look at that body of data, it will start to provide potentially an early signal. And I think in that sense, the things that I will personally be looking at, I think we'll be focused on, first and foremost, it's clinical end points. It is the clinical endpoints that matter most to these patients, obviously.

We are developing the medicine to try and prevent the sequela of disease. And so obviously, that includes things like metabolic decompensation events, hospitalization, other interventions, other progression signs of their disease. And importantly, that's something you really only measure over time as opposed to a biomarker, which I'll get to in a second. You really need to see about what that looks like over time. Now the benefit of where we will be this year is that we will have a reasonably large amount of time for these small number of patients on drug. And so that's something that we'll be focused intensely on. But again, it's [small in] and that we'll be looking at.

When it comes to biomarkers, we're looking at a range of biomarkers. It's important to note there are no validated biomarkers in this disease. It's not even guaranteed that we discover a validated biomarker in this disease. But obviously, it will be helpful as an evidence of pharmacology and the potential for benefit in clinical endpoints that we do try and measure those.

And so we're looking at a range of biomarkers. We've described many of the ones that are associated with the disease. And that will be other data that we will have as we pull together these first couple of cohorts and we have a cogent story to tell around them. And the balance of the clinical endpoints and the biomarker data together will help us decide whether we've found the correct dose to move forward or whether more work is needed to find a more optimal dose for this patient population.

I think the encouraging thing is, as we stand today, is that we do know there are patients that have been on drug for quite a long period of time. And that longitudinal experience allows us to look at clinical endpoints and also gives us some good indication, hopefully, where we're going to be on safety, which is obviously essential for this medicine to move forward.

Operator

Our next question comes from Tyler Van Buren with Cowen.

Tyler Martin Van Buren - *Cowen and Company, LLC, Research Division - Analyst*

So the Ontario study provides some interesting initial evidence that the fourth dose is beneficial. And you mentioned the populations that should get the fourth dose. So how big in aggregate is this population in total? What percent of the U.S. and global population do these patient groups comprise?

And the second question was just a follow-up on prior reflections to make sure that I'm clear. Did you say that the average selling price per Spikevax dose in 2022 will be lower than '21 due to COVAX orders? And does this not account for a potential increased price from future U.S. orders? And could these offset that decline in ASP, especially if you sell a sizable portion of doses at year-end at that $60 per dose price I believe you just mentioned per the CMS announcement?

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

Very good. Go ahead. Yes.

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

Sorry. Go ahead, David, you take the first one, and then I'll comment on the...

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

Yes. So if I track that, in terms of pricing, that's correct. We have had and we continue to have, based on the customer mix this year versus last year, we had indicated that we'll have a year-over-year decline in the average price of product being sold when we look at the $21 billion of APAs compared to last year's actual.

And the key contributor to that decline for the year is, in fact, the inclusion of COVAX volume in the confirmed APAs that we previously were discussing. So that contributes to an average sale price decline. Will that sale price on average in 2022 change from that outlook? Yes. It can to the extent there were change in volume for COVAX, including if it were some -- of the volume were to defer beyond '22 into '23, for example, that would improve your average price calculation.

And then likewise, to the extent which we've indicated, we have an expectation of additional sales of product in 2022 for the fall season, including potentially for private market should that develop. That would then presumably have a favorable impact on the average price. So hopefully, that is clear.

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

And just to comment on the number of individuals who we think at high risk. Clearly, it can change as we see the vaccine -- we've seen with the epidemiology of the virus, as Stephen commented earlier. But just going back to our Vaccines Day earlier, we think that, that high-risk population is somewhere in the range of about 1.7 billion people worldwide.

Tyler Martin Van Buren - *Cowen and Company, LLC, Research Division - Analyst*

Okay. Congratulations again, David, on your second retirement.

Operator

Our next question comes from Cory Kasimov with JPMorgan.

Tiffany Sun - *JPMorgan Chase & Co, Research Division - Analyst*

This is Tiffany on for Cory. So as the U.S. government hasn't procured a budget for boosters this fall and if they continue to not place orders, can you walk us through some of the implications of what that privatization potentially means and how the company is thinking about it? You mentioned potentially higher prices, but anything from market research that might suggest demand change or how you're thinking about discounts, et cetera?

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

Sure. Tiffany, this is Stephane. So indeed, while we are in discussion with the U.S. government, as you would assume is appropriate, we're also working towards assuming that there's no government order or American order for vaccines. We want to make sure we can protect as many Americans as we can with the vaccine. And so with our commercial U.S. team, we're working very diligently, and David and I have spent quite some time in the last weeks and months to make sure that we have all the wholesaler contracts and all the pieces you need to be able to be commercial in the [rational sense] of the world in vaccine.

And we have quite a number of executives that are vaccine self-experienced in the U.S. on our team. And so while we hope that the U.S. government, like other countries in the world, will decide to place another like we've done in the past to allow the maximum number people, recruiting people and ensure to get vaccinated, we're getting fully already assuming the day 0 order from the U.S. government, just in case if that happens. That is a 100% private market in the fall, and the company will be ready for that.

Tiffany Sun - *JPMorgan Chase & Co, Research Division - Analyst*

Okay. Great. And then just a second one. So how should we think about operating expenses moving forward and potentially steering away from COVID as a big driver there? Will it be pipeline dependent or something else?

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

Yes, it's a good question. We've tried to give you the indication of the trends for expenses across the business. What I would expect to continue is a very significant investment in R&D as that pipeline progresses and expands. And I would say it shouldn't be surprising if you see -- if you move past 2022 that you'll see a continued increase in the investments in that area, presuming success which we're feeling very good about.

And then in terms of the other considerations, in terms of cost, in terms of SG&A and -- if you look at the business now, we've substantially built out the company, as we've talked about, as a global commercial enterprise. So I think we're while perhaps not precisely there yet, we're largely there in terms of if you look at the structure of the business globally. So that I think you might consider to be more of a steady state. So that would be my initial comments on the thinking on that.

Operator

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

Unidentified Analyst

This is Alex [Hammonds] on for Geoff Meacham. So on BD, how do you think about partnerships versus acquisitions? And how large of a deal would you be willing to consider? And then if I may, can you provide your thoughts on the RSV competitive landscape? And any color on time lines for the readout?

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

Yes. So this is Stephane. Partnership versus M&A., I think it's really a question of risk and then willingness of sellers to sell, because there needs to be two to tango. And so as we've done from our deal with Metagenomi, whether we do a partnership in terms of licensing for Metagenomi, because we are very excited about the science and the team that we discovered over time and with diligence. We thought at this stage of the generating technology of that company, it was not the best thing for us to do from a risk-adjusted basis to acquire the company.

And in terms of M&A, we would be very happy to buy the right company that we really believe will drive value to Moderna on a risk-adjusted basis. In terms of deal size, we're looking at a lot of different things. But again, we are staying very disciplined. We are here to create value, not to do things just for the sake of doing things. As you know, a lot of us have a significant share in the company, and we are already focused on creating value.

So the BD team, as I said, is the most busy they have been in a long time. We're looking at a lot of things literally around the world because the best science is not always in this country. If there's a lot of amazing science in this country, but there's a lot of other smart people around the planet. And we think we modernize infrastructure and capital, actually has a lot of technology that we could partially scale up where there's production teams that have cool science, but not necessarily the right balance sheet and our infrastructure to scale and to maximize patient impact.

Stephen, you want to take technology?

Stephen Hoge - *Moderna, Inc. - President*

Sure. So on RSV, so first, where we are on the data of our program, 1345, we think the titers, the neutralizing antibody titers, GMTs we've seen, look really strong relative to competitors. And we also feel quite optimistic and positive about our history of generating strong T cell responses against respiratory viruses. And the mRNA platform, in particular, has demonstrated, we think, through the COVID pandemic, pretty remarkable performance relative to more traditional approaches. And so the combination has us optimistic. We ultimately don't need to go demonstrate in a clinical trial that potential benefit. And that's a Phase III study that we're now in and going full speed at.

That Phase III study, like our other respiratory virus efficacy studies is a case-driven design. And so at the end of the day, we have to enroll people, vaccinate them and then make sure that we accrue enough cases to conduct the interim and final analysis. That is something that we're trying to make sure we're enrolling in geographies where we expect and anticipate RSV surges.

And there have been recent reports from a competitive landscape perspective of others modifying their studies to increase the number of enrolled subjects in their pivotal studies because perhaps they haven't yet hit that rate of case accrual. In some ways, we think that provides us an opportunity to close even more ground because now we're all rapidly working to try and demonstrate the potential of RSV vaccines to help this same older adult population. So it's beyond our control to know when exactly we will have those cases accrued. But obviously, we'll be working hard to make sure that we're as enriched as possible.

Now from an overall competitive perspective, other than the vaccine -- the freestanding RSV vaccine in older adults, which as I said, we're quite optimistic about the GMT -- T cell response to the platform, we are also studying combos. Because at the end of the day, these are not the only virus -- it's not the only virus affecting these populations.

And so I'll remind you that we have an RSV flu, COVID combo, which we are going to start a clinical study on, we believe, this year, which would be a combination of all of the 3 most common respiratory pathogens that are impacting older adults. And as I said, a moment ago, we fully enrolled our RSV and human metapneumovirus combination, which I'll remind you, that's in the pediatric population and another important population for RSV, where both of those viruses can lead to morbidity in young children.

And so we are continuing down our strategy of making sure that we're not just addressing 1 pathogen, but that we're providing the best potential health intervention. So that includes that combination strategy. And over time, we think as we demonstrate the potential of our platform against any individual virus, the part of the real value we will deliver to health care systems and patients is the ability to do those combinations quickly to reflect the epidemiology, the underlying patient population is different in younger kids than it is in older adults.

Lavina Talukdar - *Moderna, Inc. - Senior VP & Head of IR*

Kevin, we have time for one more question.

Operator

Okay. Our last question comes from Joseph Stringer with Needham & Company.

Joseph Robert Stringer - *Needham & Company, LLC, Research Division - Senior Analyst*

I had one on the rare disease programs. And just curious, you have the PA in MMA and clinical development here in an initial readout in PA. How much is the PA readout? Would that be sort of derisking in terms of bringing additional rare disease programs into the clinic? Has it been more of a -- some of the hurdles and challenges to expanding that area of the pipeline? Is it then more on an indication-specific basis? Or have you been sort of waiting for the initial proof-of-concept readouts to bring more programs into the fold? Or has it been more of influenced by sort of the focus on COVID and potentially headwinds related to the COVID pandemic? Any additional color on that would be helpful.

Stephen Hoge - *Moderna, Inc. - President*

Great. Thank you for the question. And it is going to be a mix of all of the factors you listed. So first, let me talk about PA and what that readout means for us as a platform.

So it is our most advanced rare disease platform with an mRNA LNP targeted for those metabolic diseases. And in that sense, MMA and PA, both will provide validation that the technology risk associated with that are addressed. And that would cause us, from a derisk perspective, from a strategy perspective to expand the number of diseases we go into quite quickly there that could use that same technology.

We have been waiting for that readout. We haven't sat on our hands though. I'll note that we have a third program, GSD1a with an open IND that, as we've said before, in this slightly -- is in a different lipid nanoparticle system. So we've continued to look at whether other improvements could help. And we'll continue to look at those. But obviously, if we have a very strong signal out of PA, we will be on gating other programs that can benefit from the technology that with NBD risk from the PA program.

When it comes to just the challenges of conducting these studies, I'll remind you that these are, unfortunately, very ill children often in these studies and relatively rare diseases. And so yes, it has been difficult throughout the pandemic in an experimental context to bring people in.

And there have been several times during the last 2 years that we have actually taken an active decision with investigators and families not to be enrolling people because, obviously, bringing sick children into hospitals was exposing them to risks around SARS-CoV-2. There are obviously also even more recently in the Omicron surge. Lots of disruption that these institutions have faced as staff and others have become ill, and therefore, we can't connect the studies.

We hope that a lot of that is behind us now as we move to an endemic phase for SARS-CoV-2 and that, that will -- that we will really see a pickup in our ability to continue to execute the study. So we're proud of the progress we've made in the last year.

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

Well, thank you very much for joining us today. And we look forward to meeting a lot of you in person in Boston when we do the R&D day 2 weeks from now. Have a great day. Thanks.

Operator

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