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MRNA.OQ - Q4 2023 Moderna Inc Earnings Call

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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the Moderna Fourth Quarter 2023 Conference Call. (Operator Instructions) Please be advised, today's conference is being recorded.

I would now like to hand the conference over to your speaker today, Lavina Talukdar. Please go ahead.

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 fourth quarter and full year 2023 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 Stéphane Bancel, our Chief Commercial -- Executive Officer; Stephen Hoge, our President; and Jamey Mock, our Chief Financial 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'll turn it over to Stéphane.

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

Thank you, Lavina. Good morning or good afternoon, everyone. Thank you for joining us today. I will start with a review of 2023. Jamey will then present our financial results. Stephen will then review our late-stage clinical programs, and I will close by sharing our 2024 priorities.

Let me start with our mission: Moderna's commitment to deliver the greatest possible impact to people through mRNA medicines. In 2023, every member of the Moderna team helped to advance our mission, which is a driving force that motivates our team every single day. We impacted more than 100 million people around the world, and we advanced our development pipeline across all of our franchises, including infectious diseases, oncology and rare disease.

2023 was a difficult year as we transition from a pandemic to a seasonal endemic market. We reported sales of $6.1 billion for 2023, which was at the low end of our financial framework range. These sales exclude the recognition of $600 million of deferred revenue from Gavi.

In the U.S., the vaccination rate was down year-over-year. We were pleased that our U.S. commercial team drove an increase in our retail market share from 37% to 48%. Outside of the U.S., we were not able to compete in the EU market in the second half of 2023 due to a competitor contract, and our performance led to a low market share in Japan. We did have a strong performance in Israel, Switzerland and Taiwan.

We took several important actions in 2023 that we set our commercial COVID business up for success. We resized our manufacturing footprint, which has been established to support capacity at pandemic levels. We exited contract manufacturing relationships and reduced inventory levels. These initiatives will improve cash flow from our COVID business moving forward.

We also flattened the commercial structure. All regions report directly to me now for more targeted sales execution and also a better integration with global teams. We focused our R&D spending and our SG&A expenditures towards near-term growth and higher return on investment projects.

While sales were challenging in 2023, our development team had a great year, with excellent progress across many of our late-stage pipeline programs. In 2023, we advanced our pipeline and now have 9 late-stage programs. Let's start with respiratory vaccine.

For RSV, we filed for approvals around the world. We reported positive data from our flu P303 study, and we are fully enrolled in the Phase III studies for our next-gen COVID, mRNA-1273, and flu plus COVID combination vaccine, mRNA-1083.

In our latent franchise, we are very excited that our Phase III CMV trial is now fully enrolled.

In our individualized neoantigen therapy program, or INT, where we partner with Merck, Phase III studies in adjuvant melanoma and non-small cell lung cancer are enrolled. We purchased and are currently building out a manufacturing site in Marlborough, Massachusetts to enable commercialization of our INT program. Already this therapy programs continue to progress well.

We're in dose selection for the registrational study of our propionic acidemia program. In MMA, we are pleased to see improvement in biomarkers and clinical outcomes.

In research, we made 6 external investments, including 1 acquisition, which we expect will increase the strategic reach and also the breadth of our mRNA platform.

Now turning to our 2023 financial summary. We reported GAAP revenue of $6.8 billion, a net loss of $4.7 billion, primarily driven by mostly noncash charges of $3.7 billion related to resizing of manufacturing and the tax valuation allowance. We are pleased to end the year with cash and cash investments of $13.3 billion.

Let me turn to Jamey for more color on the financials.

James M. Mock - *Moderna, Inc. - CFO*

Thanks, Stéphane, and hello, everyone. Today, I will review our financial performance for both the fourth quarter and the full year of 2023. I'll also provide our financial framework for 2024. Let me start with a review of our commercial performance this year.

In the first half of 2023, we reported product sales of $2.1 billion, with the majority of sales from advanced purchase agreements signed for delivery in 2022 that were deferred into 2023. We do not expect these sales to repeat in 2024.

In the second half of 2023, we recorded $4 billion in sales from seasonal endemic demand, and an additional $600 million from deferred revenue related to Gavi.

Sales in the fourth quarter were $2.8 billion, with $0.8 billion in sales in the U.S. and $0.6 billion in Europe and $1.4 billion in the rest of the world, including the deferred revenue from Gavi.

For the full year 2023, product sales were $6.7 billion, comprised of $1.7 billion in sales in the U.S., $1.4 billion in Europe and $3.6 billion in the rest of the world, again, including deferred revenue from Gavi.

Moving to Slide 10. As mentioned, net product sales were $2.8 billion this quarter, a 43% decrease from last year. This was largely attributable to the anticipated reduction in sales volume, which was partially offset by a higher average selling price. This decrease is indicative of the evolving market dynamics as we navigate the transition of the COVID-19 vaccine market towards a more predictable seasonal pattern like traditional flu vaccines.

Cost of sales was $929 million, down from 39% of net product sales in the previous year to 33% this year. This is a demonstration of our strategic efforts in Q3 to resize our manufacturing footprint, which, as expected, led to additional charges in Q4 of $169 million, primarily related to the wind-down of certain contract manufacturing operations. Additionally, cost of sales also includes inventory write-down of $322 million, reflecting revised demand forecasts.

R&D expenses increased by 16% to $1.4 billion. This uptick reflects our commitment to advancing our late-stage clinical development programs, particularly with our RSV vaccine, CMV vaccine, combination vaccine against flu and COVID-19 as well as our INT program. The increase also included an upfront payment of $120 million associated with the strategic research and development collaboration with Immatics.

SG&A expenses were $470 million, up 25% year-over-year. The increase in spending was primarily due to the expansion of our commercial operations, particularly in the U.S. market.

Income tax was a benefit of $147 million for the fourth quarter of 2023, largely attributable to the tax benefits as part of finalizing our 2022 U.S. tax return.

Net income for the quarter was $217 million compared to $1.5 billion in the fourth quarter last year. Diluted earnings per share was $0.55 compared to $3.61 in 2022. We closed the quarter with a strong cash position of $13.3 billion, which is slightly higher than the $12.8 billion we had at the end of the prior quarter.

Now let's turn to our annual performance on Page 11. Net product sales for the full year 2023 were $6.7 billion, a decrease of 64% from the previous year, mainly due to lower sales volume of our COVID-19 vaccine. As mentioned earlier, this includes the recognition of $0.6 billion from the deferred revenue related to Gavi. Excluding this item, our sales of $6.1 billion were still in line with the framework we provided for the full year.

Cost of sales for the full year represented 70% of net product sales, a substantial increase from 29% of product sales in 2022. This shift is largely attributable to our strategic efforts to optimize our manufacturing operations, resulting in charges of $1.6 billion and other manufacturing and distribution costs over reduced sales volume. Overall, cost of sales came in at $4.7 billion, slightly below the $5 billion we provided in our latest framework.

Research and development spend was $4.8 billion, and SG&A was $1.5 billion, both in line with our expectations. Our income tax provision was $772 million for the full year 2023.

During our Q3 earnings call, we discussed the requirement under GAAP to establish a valuation allowance against deferred tax assets when the current year and cumulative income projection for the next 3 years is in a loss position. It's important to note that future income from products not yet approved by regulators are excluded from these income projections, which restricts us to just our COVID vaccine, and it does not include expected future launches. This valuation allowance does not impact future cash flows, future tax returns or the company's ability to utilize deferred tax assets in future periods.

Net loss for the year was $4.7 billion compared to an income of $8.4 billion last year. The decrease in profit was primarily due to lower product sales and higher R&D expenses in 2023. Diluted loss per share was $12.33 compared to the diluted earnings per share of $20.12 in 2022.

So now let's move to Slide 12. We wanted to provide you additional perspective on our full year financial results by presenting them alongside a summarized version that excludes the impact of the Gavi deferred revenue recognition or resizing charges and the tax valuation allowance. Our total GAAP net loss for the full year was $4.7 billion. However, when excluding these primarily noncash items, the net loss is reduced to $1.6 billion.

Now let's turn to our 2024 financial framework on Slide 13, which is mostly in line with what I shared on our Q3 call. We expect net sales for 2024 of approximately $4 billion, which we think will be a low point as we expect to return to growth in 2025. Sales in the first half of the year are expected to be approximately $100 million, reflecting the strong seasonality of respiratory vaccines.

We expect cost of sales of approximately 35% of product sales, in line with our cost of sales framework, which we introduced in our Q3 earnings call last year.

For R&D, we expect full year expenses to be approximately $4.5 billion, down from $4.8 billion in 2023. And for SG&A, we expect full year expenses to be approximately $1.3 billion, down from $1.5 billion in 2023. We also expect taxes to be negligible in 2024.

In our Q3 earnings call, I provided our Moderna operating principles, which largely centered around a very disciplined approach to capital allocation. Our #1 priority has been and will continue to be reinvesting in the business. In addition to the investment into our pipeline, we expect capital expenditures in 2024 to be approximately $0.9 billion as we mostly complete the construction of our facilities across the globe.

Our teams are laser-focused on operational improvements for both expense management and working capital. As a result, we expect to end 2024 with approximately $9 billion in cash.

I will now turn the call over to Stephen.

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Jamey. Good morning or good afternoon, everyone. Today, I'll do a quick review of our clinical highlights from our late-stage programs in 2023 and then look ahead to anticipated milestones in 2024.

While we have over 40 programs in development, we will focus on our late-stage pipeline, which consists of 9 programs across 4 franchises, all made significant progress in 2023. Four of these programs are in our respiratory vaccine franchise. We hope to launch all of these potential products by the end of 2025. I'll discuss this further in a moment.

The other 5 late-stage programs are spread across latent vaccines, oncology therapeutics and rare disease therapeutics. We hope to begin launching these beginning in 2026, and I'll discuss our progress in these areas as well.

In infectious disease vaccines, we've achieved many important clinical milestones in 2023. Within our respiratory vaccine franchise, we filed for RSV vaccine approvals in many countries around the world. We recently presented follow-up data from our Phase III study at the RSVVW meeting that I'll recap in a moment.

In our mRNA-1010 flu program, our Phase III P303 study met its primary safety endpoints and hit all 8 co-primary immunogenicity endpoints against all strains of influenza. We're also excited that we fully enrolled the Phase III immunogenicity and safety study of our next-gen COVID vaccine and the Phase III immunogenicity and safety study of our flu and COVID combination vaccine.

In our latent and other vaccines franchise, we're proud of the great progress our team made to complete enrollment in the Phase III study of our CMV vaccine in 2023. That study is now accruing cases towards its first interim analysis of efficacy.

On Slide 17, I want to briefly review the primary analysis for our RSV vaccine, which was first shared in January of 2023. The study met its primary and key secondary endpoints, leading the DSMB to recommend unblinding. Vaccine efficacy was 83.7% against RSV with 2 or more symptoms of lower respiratory tract disease at a median follow-up of 3.7 months with a wide range of 2 weeks to 12 months of total follow-up. The primary analysis showed -- also showed 82.4% and 68.4% vaccine efficacy against 3 or more symptoms and acute respiratory distress, respectively. These data were recently published in the New England Journal of Medicine in December of last year.

We've continued to follow the participants in the trial and announced follow-up data at the RSVVW conference earlier this month. An additional analysis showed sustained vaccine efficacy against RSV, with VE of 63.3% against RSV lower respiratory tract disease with 2 or more symptoms through a median follow-up of 8.6 months and a maximum follow-up of 17.7 months. The vaccine efficacy was 74.6% against RSV lower respiratory tract disease associated with shortness of breath, which has been shown to be a key driver of seeking a higher level of medical care and the associated burden costs.

Now Slide 19 summarizes the overall timing of enrollment, primary efficacy analysis and subsequent analysis overlaid against the epidemiology of RSV over the 2 seasons that have now contributed to the efficacy in the trial. Our trial enrolled steadily over 13 months between November 2021 and December 2022. As a result, the primary efficacy analysis included cases from both the smaller RSV season of 2021 and 2022 and a much more significant RSV season of 2022 and 2023.

Due to enrollment throughout the year, the median follow-up of the primary analysis was 3.7 months. But as I noted, the maximum follow-up was 12 months. The primary analysis met its success criteria leading the study unblinding.

We continue to preplan additional analysis on April 30, 2023. At that analysis, the median follow-up was 8.6 months, with a maximum follow-up of 17.7 months, or put another way, approximately 17,000 participants were between 9 and 18 months of study follow-up at the time of the analysis, with many completing their second RSV season on the study.

Per protocol, we are continuing to follow cases through 1 year, but it is evident from the epidemiology, very few cases would be expected in the 6 months after the April 30 cutoff date from the last analysis.

In summary, we are pleased that the data shows sustained efficacy through 2 seasons, including the large RSV season of 2022-2023. And we look forward to providing further updates from this ongoing study.

We also achieved clinical milestones across our therapeutic franchises in 2023. In oncology, our individualized neoantigen therapy developed in partnership with Merck began Phase III clinical studies in both adjuvant melanoma and non-small cell lung cancer. Both Phase III trials are now actively enrolling.

Our primary analysis from the Phase II study was recently published in The Lancet, giving greater detail on the 2-year follow-up data that we had released in 2022. Now in December of 2023, we shared top line follow-up data from that same Phase II study in adjuvant melanoma patients confirming the durability of the initially reported responses. At a median follow-up of now 3 years, the recurrence-free survival and distant

metastasis-free survival remained extremely favorable, with a reduction of the risk of recurrence or death by 49% and a reduction of the risk of distal metastasis or death of 62%. Both results were highly statistically significant at 3 years.

And in PA and MMA, our most advanced rare disease therapeutic programs, we continue to see positive clinical data in our Phase I/II studies, including improvements in biomarkers and clinical outcomes such as metabolic decompensations.

Now turning to Slide 21 (sic) [Slide 22]. While we're proud of the progress in 2023, we have much more ahead in 2024. Let me take you through some of the late-stage milestones we anticipate for this year. I'll start with our respiratory franchise, where we are targeting the first approval for our RSV vaccine beginning in the first half of 2024, with commercial launches shortly thereafter.

With our flu vaccine, we're in discussions with regulators about potential submissions for approvals. And we expect to begin filing this year.

Phase III data from our next-gen COVID vaccine is expected in the first half of 2024, which will inform the next steps. And we expect Phase III data for our flu and COVID combination vaccine this year.

In latent vaccines, we are looking forward to potential efficacy data from our CMV Phase III study.

In oncology, we expect continued progress in rolling our 2 Phase III studies in INT for adjuvant melanoma and non-small cell lung cancer. We also expect to expand into additional tumor types this year.

And finally, in rare diseases, we expect to move into registrational studies for both PA and MMA in 2024. It will be a very busy year, and we look forward to sharing progress with you as the year progresses.

With that, I'll turn the call over to Stéphane.

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

Thank you, Stephen and Jamey. For Moderna and the patients we serve, 2024 is all about execution: execution in commercial, execution of our late-stage pipeline and execution with financial discipline.

Starting with commercial. First, our COVID vaccine. We will continue to work with health authorities to increase vaccination rates and improve public health by reducing the substantial burden of disease from COVID in this upcoming 2024-2025 season. While I am pleased with the U.S. market share outcome of the current season, I believe we can and must do better on vaccination rates. Our team are actively working on it already. A few weeks ago, the EU published a new mRNA COVID vaccine tender, up to 36 million doses per year for up to 4 years. Our team is actively working to respond to this tender. We are prioritizing our commercial focus on specific markets around the world to deliver where it matters the most.

Moving to RSV vaccine candidates. We are very excited about launching the RSV vaccine this year. That will be the launch of our second product our mRNA platform is delivering. The FDA PDUFA date is May 12. If the outcome is positive, we anticipate that ACIP will include mRNA-1345 on the agenda in late June.

In Europe, we expect Germany to launch in 2024. We also expect Australia to launch this year, while other markets will likely launch in 2025.

In many markets around the world, we need to secure regulatory approval before we can participate in tenders. As communicated last year, given expected approval outside the U.S., Germany and Australia, we anticipate launching early in this market in 2025.

The RSV market is estimated to be a $10 billion opportunity, consisting roughly of $6 billion to $8 billion in older adults and $2 billion to $4 billion in the pediatric and maternal setting. In 2023, the first year RSV vaccine launches, consumer awareness of RSV and demand for RSV vaccine was strong. The 2023 adult RSV vaccine market was around $2.5 billion. This is quite impressive given it was the first year RSV vaccine were available,

they were not even available for a full year, and the products were not approved in many countries. With 2023 RSV vaccination rate as a small percentage of a total addressable market, we are quite excited to launch our product into this large and growing market.

Let me now turn to our RSV vaccine profile. We believe we have the best profile to serve patients and compete in the RSV market, efficacy, safety and ease of use. Our clinical data shows strong vaccine efficacy. We have a well-established safety and tolerability profile that leverages the same mRNA technology that has been delivered in over 1 billion COVID vaccine. Additionally, we have not seen any case of Guillain-Barré Syndrome, or GBS, in our Phase III trial.

We expect to be the only company to offer an RSV vaccine in ready-to-use prefilled syringe, or PFS. Our one-step administration compares well relative to competitive products and require multiple preparation steps by pharmacists and clinicians. As you know, one of our competitors' product requires 9 steps of preparation for each consumer needing a RSV vaccine, and the other competitor's product requires 4 steps of preparation.

With over 90% of the U.S. RSV vaccine given to date in the pharmacy setting, PFS presentation offers ease of use, time savings and the potential to reduce medical errors. Given the labor shortage in retail pharmacy channel, we anticipate our PFS presentation will be welcomed by pharmacists in a very busy respiratory vaccine season, where pharmacists need, in addition to their regular tasks, to administer flu vaccine, COVID vaccine and RSV vaccine.

Today, we talk about how much progress we made in the late-stage pipeline in 2023. This year, we look forward to continued execution and reporting milestones in each of these programs.

If you look at this slide, it is going to be a very busy and very exciting year, with multiple Phase III readouts like the COVID next-gen, also flu plus COVID Phase III data and potentially CMV Phase III data. But also, we're going to be filing products like flu, which will be our third product filed, and of course, approval in many countries around the world for RSV.

Finally, we are all committed to exercise financial discipline across the business. While we have resized our manufacturing footprint in 2023, we will continue to find ongoing cost improvements in manufacturing. We will reduce operating expenses in R&D and SG&A and prioritize program in R&D with a near-term commercial potential in areas of unmet medical needs.

Overall, our CapEx will be up mostly -- modestly in 2024 compared to 2023, and we'll mostly complete construction of several important plants in Marlborough, Massachusetts for INT and Canada, U.K. and Australia. In 2025, we expect CapEx to be down significantly.

We're also targeting working capital improvement. And importantly, as you know, we are adopting AI across the business, which we expect to save time, increase productivity and drive scalability in addition to cost savings. Our use of AI is increasing by the week. And new use cases are exciting to see how our teams are embracing this new tool across the business.

In summary, 2024 is an important year of execution across our company, one that we set the stage for the next several years. I am very excited by how our company is positioned. I believe 2024 will be a year where many observers of Moderna go from thinking of us as a COVID vaccine company to seeing Moderna as an mRNA platform company with several products approved and more approvals on the way for 2025 and beyond. Over the next few years, our ability to deliver on our mission will increase significantly and be very meaningful for our teams.

With that, operator, we'll be now happy to take questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Michael Yee with Jefferies.

Michael Jonathan Yee - *Jefferies LLC, Research Division - MD & Senior Biotechnology Analyst*

Focusing on RSV. I know you made a number of nice comments about comparing the data. Maybe you could talk to 2 or 3 points. One is perhaps how it will work in the commercial market in the U.S. with contracting. Is that contracting season? Or do you have to have contracts? And how does that work between the 2 different other competitors?

And secondly, how would that work at the pharmacy level when either patients or doctors are making the selection given the fact that Pfizer and GSK both had similar sales but different profiles? Maybe talk to those 2 different things and how you expect that to play out for this year.

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

Great. Thank you, Michael. It's Stéphane. So in terms of contracting, obviously, we cannot start contracting now because our product is not approved. But our medical team has been quite engaged across the board at medical conferences, talking to health care professionals and sharing the great data that was published in December, as you know, from our Phase III in the New England Journal of Medicine. So we have active discussions.

There is quite high excitement about the possibility, again, if the product was to be approved, to get a prefilled syringe product. As we discussed in my remarks, as you know, labor shortages are a big issue in pharmacy. For any of us that has gone through a pharmacy in the fall, you could see it was very busy, sometime a bit too hectic. And so the leadership of the big retail pharmacies is very engaged to think about COVID versus RSV and how to simplify the workflow, how to reduce medical errors, which is why those medical discussions that we're having so far give me a significant hope that our products will be meaningful tools for our customers.

Operator

Our next question comes from Gena Wang with Barclays.

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

I have 2 very quick questions. First one is regarding the RSV vaccine. What portion of 35,000 to 36,000 participants that completed 2 seasons? And regarding February 29 ACIP meeting, what additional data you will be presenting?

And very quickly on 2024 guidance. Now we have a better understanding of both COVID and RSV market size for 2023 and 2024 season. What could be the upside or downside for your 2024 revenue guidance of $4 billion?

Stephen Hoge - *Moderna, Inc. - President*

Great. Thanks, Gena. I'll take the first part of that. So I actually can't -- I don't know, off the top of my head, the proportion because they're both in Southern and Northern Hemisphere participants that were enrolled in the study. And so counting the 2 RSV seasons will depend upon that.

It is a sizable proportion because as I said, the maximum follow-up at the additional analysis is about 18 months. Median was 9 months. And so by definition, about half, as you just said, about 17,000 participants were between it. And we did enroll pretty continuously over 13 months, not exactly evenly, but pretty close to it. So I don't want to give you an inaccurate number, but I would suspect it is a pretty sizable proportion because of that steady, pretty consistent enrollment over the course of 13 months. It's not exactly equal, but it trended that direction.

As far as additional data for the ACIP meeting, we'll obviously continue to provide updates from any additional analysis we're doing on durability. We obviously have immunogenicity data as well as data across different subpopulations. And if we're fortunate enough to have the opportunity to present at the ACIP, we will, of course, listen to the committee on anything they would like to see as well on the performance of mRNA-1345 as

a vaccine and the performance of the vaccines in general in terms of durability as it guides decision-making around repeat dosing or boosting on some schedule in the public health.

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

Thanks, Stephen. And Gena, it's Stéphane. On the upside and downside on the sales for this year, I think on the upside, obviously, the COVID in Europe, as I just mentioned, we couldn't participate in the market last fall. The new tender is an opportunity for us to participate. Quite a number of doctors, hospitals, public health leaders have actually complained that the Moderna vaccine, given the higher efficacy reported for reduction of hospitalization, was not available, especially for the elderly, for immunocompromised people. So that's an interesting upside.

Of course, the vaccination rate in the U.S. as we reported, the vaccination rate in the current ending season was lower than last year. As I said in my remarks, we need to do better to protect more people. And our team is actively already working in a cross-functional matter to address the VCR and increase the vaccination rates. And the other upside could be the RSV both the market growth as well as our share, how quickly can we get share from the current 2 solutions available.

On the downside, of course, the vaccination rate could be a downside. And the other one is, of course, timing of RSV launch, given we rely on regulators for the approval of products and then the public health recommendations like CDC or the different ITAGs in the different countries that could, of course, delay launches and, of course, impacting sales.

Operator

Our next question comes from Ellie Merle with UBS.

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

Just turning to the CMV Phase III, can you talk a little bit about what you would view as clinically meaningful or commercially relevant on vaccine efficacy? And if successful, also how are you thinking about use in seronegative versus seropositive patients?

Stephen Hoge - *Moderna, Inc. - President*

For sure. So thank you for the question. So in CMV, obviously, there's currently no vaccine that can prevent an infection against CMV and as it is a source of devastating birth defects, anything that provides a statistically significant reduction in the rate of infection and, therefore, vertical transmission would be, we think, terrific. Now the minimum bar that we are powering in our study with support is a vaccine efficacy of approximately 50%. As we've shared previously, anything above that would obviously beat our expectations and be incredibly exciting for the field.

We are in the Phase III study, enrolling both seropositive and seronegative participants. And part of the reason for that is that there's currently no broadly used diagnostic. And so we want to demonstrate benefit or safety in both populations because we do believe that the most likely use of the vaccine could be that it's given regardless of sero status to both seronegatives and seropositives. And there are potential benefits for seropositives that could include control of shedding or viremia or other long-term sequela of CMV, but we would have to prove those. And again, those are not something we're exploring explicitly in the current Phase III study.

So as a practical matter, from a labeling perspective and a launch perspective, our goal is to try and launch the product for both seropositives and seronegatives so that no diagnostic will be needed and it can be broadly used across populations to try and prevent the devastating effects of CMV on vertical transmission to newborn babies.

Operator

Our next question comes from Hartaj Singh with Oppenheimer.

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

You indicated that you're going to complete enrollment for CMV this year and maybe have a readout. Can you just walk us through the steps of how that would look like and maybe just give us some ideas on powering statistical assumptions?

Stephen Hoge - *Moderna, Inc. - President*

Yes, of course. Thanks, Hartaj. So we're currently fully enrolled, and we're accruing cases in that study. And I think as we've shared before, we've actually made substantial progress in a number of cases.

It is a case-driven endpoint, and we'll need to see approximately 80 cases before we'll do the first interim analysis for efficacy. That -- 81 cases, to be specific. That interim analysis for efficacy will look a lot like our other vaccine efficacy studies. DSMB will evaluate that data. And if we meet the statistical threshold, which is for early efficacy, meaning we're doing better than our minimum of 49.5% vaccine efficacy, then they will, at that moment, tell us to unblind and share the results. And of course, we will share them broadly with the world.

If, for whatever reason, we don't quite have the statistical power in that first interim analysis of efficacy, the study is powered to continue on and continue to recruit cases towards a final analysis of efficacy. Now given the rate of -- the final analysis at 112 cases.

Now given the rate of a case accrual that we're currently seeing in the study, we do expect that we will have more than enough cases this year. We are, therefore, pretty confident that we are going to be seeing a readout from the interim analysis, possibly even the final analysis for efficacy in 2024. But again, since it's case- and event-driven, we just have to bide our time. And ultimately, we will depend upon the DSMB to tell us whether or not we've met that statistical threshold.

Operator

Our next question comes from Luca Issi with RBC Capital.

Luca Issi - *RBC Capital Markets, Research Division - Research Analyst*

Maybe, Stephen, on INT, maybe can you remind us what's your latest thinking in terms of potential for accelerated approval there for melanoma?

And then maybe on the additional tumor types that you guys and Merck are thinking about it, can you just maybe talk about what are tumor types that you're contemplating and whether those tumor types are going to be in the adjuvant settings or in the metastatic settings?

And then maybe on RSV quickly, can you just maybe expand on durability in the context of your competitor? Is there a scenario where ACIP recommends the GSK vaccine for every other year versus your vaccine for every year? Any color there, much appreciated.

Stephen Hoge - *Moderna, Inc. - President*

Quite a few questions there. I'll try and get them all. I apologize if I forget any one. So first, on the question of INT and accelerated approval in the adjuvant melanoma setting. So as we've said before, we continue to be really excited about the data and are excited to start looking to talk to regulators about it.

There have been 3 things that we've tried to say that had to be true for us to believe it was appropriate to even ask about accelerated approval. The first was we had to see durability. And clearly, the data that we just saw from December just 2 months ago shows that durability and really a clear statistically significant result where the comparator arm, the control arm, looks really just like the labeled data. And so we're incredibly encouraged by that durability. That was criteria one.

But the second and third are still there and really important. The second is that we have to substantially enroll the confirmatory Phase III study. For an accelerated approval in this space, we do believe we have to show we've really already done the diligence to allow that confirmatory data to come in so that 3 or 4 years from now, that further readout would confirm anything that would happen in accelerated approval context.

And then the third and perhaps now increasingly important criteria was that we had to establish the commercial manufacturing facility. So as we've announced, we've been building a facility in Marlborough, Massachusetts. It will be a purpose-built, personalized, individualized neoantigen therapy facility that is ultimately what will be licensed to create this product for the world, whether it's in an accelerated context or in the future with full approval. That facility is coming online. We look forward to hosting many of you and others in tours as we bring it online. But without that facility, there isn't really a product here to talk about.

And so all 3 of them are essential. We're making progress on all 3. And I think the most exciting thing is what you were just alluding to, which is the durability of the benefit we've been seeing really causes us to now lean into completing -- working hard to complete the enrollment of that confirmatory study criteria 2 and finish the build-out of that Marlborough facility, which is the third criteria.

Now on the point of other indications that we're going after, the -- we will -- I will defer to our partners, Merck, on the specifics. We will do it together at the right time, opening up additional Phase III and confirmatory studies. We do expect to open multiple this year. Those include some additional adjuvant indications. They also include some potential metastatic indications, and we are looking at monotherapy indications. And they can be either in places where PD-1s, KEYTRUDA may not be indicated or even earlier lines of therapy. And so all of those are under consideration. And as soon as we start those studies up and begin enrolling, of course, we'll make announcements about them with our partner, Merck.

Now lastly, on the question of RSV, we continue to be really enthusiastic about the data of our -- that our product has. And I think the durability now shown through these -- through the second large season is quite encouraging. We'll be sharing that data with the ACIP. Well, first, we have to get through the regulatory process and approval in this country, and Stéphane mentioned our PDUFA date in May. And if we have the opportunity, we'll be sharing the data with the ACIP, which includes, in our case, booster data on immunogenicity from ongoing work that has actually already previously been presented publicly at meetings.

And so just like our competitors, we have shared data of what a second dose looks like in terms of boosting, neutralizing antibody titers back up, both at 1 year, and we're also going to be looking at 2 years. And those -- all of the data ourselves, as well as that booster -- similar booster data from the competitor products, will likely be brought together to inform the ACIP's recommendation of how they think RSV vaccines should be readministered when a booster might be necessary. It really falls to the committee to make that determination, not us.

Your question was about whether we expect there to be any difference or distinction in terms of how they treat the vaccine. At this point, given the immunogenicity data and booster data that has been shared across all 3 products, which is remarkably consistent, as well as the consistent picture in terms of efficacy, including some leading efficacy for all products in the second year, we would suspect that they will continue to view the products as more similar than not and, therefore, continue with consistent recommendations. But it's really up to the committee to make that determination. At least from my perspective, I certainly think the science would support that.

Operator

Our next question comes from Salveen Richter with Goldman Sachs.

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

This is Elizabeth on for Salveen. Two questions from us. First, can you just remind us of where you stand with evaluating the RSV vaccine in the pediatric population?

And then for the Phase III CMV vaccine, can you walk us through what you've seen on durability to date and how you're thinking about the durability of that vaccine, particularly as it relates to the potential commercial opportunity in a younger adult women/adolescent population?

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

Yes. So I'll take the question. So on RSV pediatrics, we have not started the study yet. We are, of course, considering taking this into a Phase III. It is in the clinic with Phase I/II. We are waiting for the data to be able to move at the right time into the pediatric setting.

In terms of CMV, we don't have data yet on durability. Again, like we've done for other programs, when we share the data, we share the data, including durability because it's very important. As you know, the benefits of young women is they have a very strong immune system. As we've shown in our INT programs, our T cells work very well in terms of the vaccination technology of Moderna. So we really expect to have good durability over time. But again, we have to wait for the data to make such a determination.

Operator

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

Alexandria Hammond - *BofA Securities, Research Division - Associate*

This is Alex Hammond on for Geoff Meacham. So a great way to equalize vaccine efficacy results is to use a correlative of protection. So for RSV, when do you think we could have a line of sight into this type of metric? And how important could this be for our competitive dynamics?

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

It's Stéphane, so...

Stephen Hoge - *Moderna, Inc. - President*

Sorry -- small technical stuff. So I'm back. I believe I caught the end of the question, which is how -- when do we think we'll have a correlate of protection that can inform dynamics, both between products and boosting, if that's correct.

The -- we and all the other manufacturers have been sharing publicly their -- our work on a correlate of protection. We do believe that we've identified a strong candidate in neutralizing antibodies, not surprisingly, from our clinical study. We've been sharing that data with regulators, and we've been sharing the preliminary analysis with public health officials, including advisory groups and ITAGs like the ACIP.

We will be publishing that data and ultimately submitting that to our regulatory submissions as a correlate through this -- the balance of this year. And if we, and I think the other competitors are successful in establishing neutralizing antibodies against RSV as a correlate of protection in RSV, then it really will probably be the primary way that public health officials make determinations about revaccination and boosting and, ultimately, how we maintain durable protection against RSV for high-risk populations like older adults.

From a competitive dynamic perspective, once each product has established their correlate, their correlate will relate to them. But we do think there's probably going to be more commonality than not in the correlates of protection, which makes sense because at the end of the day, we're still talking about the same virus and vaccination against it for all 3 products.

Operator

Our next question comes from Terence Flynn with Morgan Stanley.

Terence C. Flynn - *Morgan Stanley, Research Division - Equity Analyst*

I was just wondering if you could provide an update on your discussions with FDA for 1010, your seasonal flu vaccine? And what's gating to filing here?

Stephen Hoge - *Moderna, Inc. - President*

Thanks. So we are speaking to the FDA and regulators around the world about what would be -- what they would like to see from a submission perspective for our first-generation of our influenza program, our mRNA-1010 programs as you referenced.

I don't have any specific updates right now. We're in those conversations as we speak. I really don't want to get ahead of them. The kinds of things we're talking about are, what's the total submission data package? What's the duration of follow-up in some of these studies? And what additional studies or data might be supportive to the application? Those conversations are ongoing. We will provide updates as and when we have them, but I have nothing further to add right now.

Operator

Our next question comes from Jessica Fye with JPMorgan.

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

For INT, can you talk about what's driving your confidence to go into metastatic settings? How's enrollment going in the Phase III melanoma trial? And I know you touched on manufacturing being important here. What's the status of that manufacturing scale-up work? And when is that facility going to be ready to go live?

Stephen Hoge - *Moderna, Inc. - President*

Great questions all. So I'll take the first part of that. So first on metastatic. So we have not formally decided or announced that we're going into a metastatic indication. We do have data from our Phase I study -- our initial Phase I study in metastatic patients, including non-small cell lung cancer. But we have not yet made a determination that we're going into the metastatic indication.

And I think behind your question is a view that I would agree with, which is to the extent that INT is going to provide a really substantial benefit, we think it is probably in earlier lines of therapy. So not just adjuvant but perhaps even Stage 1 disease or a Stage 2 disease, depending on the indication because the safety and tolerability profile is, we think, incredibly favorable and the benefits we're seeing are pretty remarkable from an immune perspective.

That said, there is still a really high unmet need in the metastatic space, and even immunotherapies like the PD-1s, like KEYTRUDA provide a substantial benefit there. And so at the right time, we may, well, choose to study the metastatic indication, but as I said -- or metastatic indications

and settings. But as I said, we have not yet formally decided to do that today. And we're really focused on adjuvant and earlier and monotherapy principally.

On the question on the manufacturing process, we're in enrollment. We have substantially scaled up our ability to enroll patients in those Phase III studies. I can assure you that with our partner, Merck, we wouldn't have opened a second Phase III study and be talking about the third if we didn't have confidence in our ability to rapidly meet the demand for -- the substantial demand from those clinical research sites for INT manufacturing.

We haven't specifically put out numbers, but suffice to say, we are rapidly enrolling in those studies, and we would expect to make substantial progress this year and even perhaps getting close to completing enrollment in at least one of those studies if it continues the trajectory.

So we're excited about the progress we've made in scaling up the manufacturing for clinical supply. We're excited about the progress we're making right now in enrolling patients in the demand that we're seeing from clinical sites. And we do believe that we've solved a lot of the -- for clinical research, for clinical development, the manufacturing requirements.

The question then becomes commercial. And as we alluded to a few minutes ago, the Marlborough site would really become the purpose-built commercial site, which means to not only be able to deliver high-quality products at high volumes but also do it at a valuable price and cost point.

And all of that work is ongoing. We've made great progress in building that site. Our goal is to establish that site for at least clinical supply this year. But we haven't provided further guidance on when we will have that fully operational for potential commercial use. And ultimately, it depends upon discussions with regulators as well.

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

Kevin, we'll take our last question.

Operator

Okay. Our last question comes from Evan Wang with Guggenheim Securities.

Boran Wang - *Guggenheim Securities, LLC, Research Division - Healthcare Equity Research Analyst*

Two from me. First on RSV. I know there are some additional studies to expand the initial population. Can you comment on when we may see data from the Phase IIIs in 50-plus and the high-risk younger adults and when you could potentially supplement a filing if everything is positive?

And then I know you commented on Australia. So just as you were thinking about -- or as you've talked about Australia as a proxy for COVID sales in 2023. Now can you comment on how [integral] Australia will be for your RSV launch and as we look for trends in COVID vaccination rates?

Stephen Hoge - *Moderna, Inc. - President*

Great. I'll quickly take the first part of that and then hand it over to Stéphane for the second.

So the additional data on 50-plus we have, obviously, immunobridging data and coadministration data, we'll be sharing that at the appropriate time with public health officials and others. It could be as soon as the ACIP. It just depends on when the data comes in, as well as the 18-plus high-risk populations.

In your question about getting this in the label, it's important to note that public health officials can recommend use even beyond the label and may choose to do that, but our responsibility will be to get it in the label. And we will need to complete the initial BLA before then we could submit the sBLA to get that data in the label. And so obviously, it would follow shortly after our hopefully successful PDUFA outcome in May.

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

Thanks, Stephen. And on Australia, so a few things. First, I mean our team has delivered a strong performance on COVID in Australia. We've been helping the government since the beginning of the pandemic. As you recall, we have announced a long-term 10-year partnership with the Australian government, and we are currently building a plant in Melbourne that is advancing quite successfully. And we are in active discussions with regulators around Australia for RSV approval.

The point I will make is that Australia, as you know, is a quite different market commercially to the U.S. It's really mostly driven by the government. So I will compare Australia more to a European market than to the U.S. market. I don't think we can draw any positive or negative correlation, and so what happened in Australia, COVID, it's what will happen in the U.S. in the full '24 with '25.

Thank you so much for the questions today. Thank you for taking the time to be with us. We look forward to talking and seeing many of you in the coming days and weeks. I hope that you will have on March 27, the Annual Vaccine Day in your calendar. We will start the presentation at 9:00 a.m. Eastern time. So have a great day, and thank you for joining.

Operator

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