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MRNA.OQ - Q2 2024 Moderna Inc Earnings Call

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OVERVIEW:

Company Summary

REFINITIV

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Stephane Bancel *Moderna Inc - CEO*

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PRESENTATION

Operator

Good day and thank you for standing by. Welcome to the Moderna second-quarter 2024 conference call. (Operator Instructions) Please be advised today's conference being recorded.

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

Lavina Talukdar - *Moderna Inc - IR*

Thank you, Kevin. Good morning, everyone, and thank you for joining us on today's call to discuss Moderna's second-quarter 2024 financial results and business update. You can access the press release issued this morning as well as the slides that we'll be reviewing by going to the Investors section of our website.

On today's call are Stéphane Bancel, our Chief Executive Officer; Jamey Mock, our Chief Financial Officer; and Stephen Hoge, our President.

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*

Thank you, Lavina. Good morning or good afternoon, everyone. Thank you for joining us today. I will start with a review of our business. Jamey will present our financial results for the quarter and thank you for our based financial framework. There will then review our clinical progress. I will then close by sharing our commercial progress and our outlook for major upcoming milestones.

In the second quarter of 2024, our respiratory franchise has shown remarkable progress and is poised to positively impact millions of lives globally each year. This is why we started Moderna to impact patients, and that is why the Moderna team is so focused on execution because of that profound impact on so many lives.

[2023] vaccine, SPIKEVAX, continues to play a critical role in combating COVID. Based on CDC data provision just ending October '23 to June '24, COVID continues to result in higher hospitalization than other respiratory viruses. We are pleased that the RSV vaccine with brand name, mRESVIA, our second respiratory product has launched in the US and has now shipped to US customers. It is poised to impact public health in the US this year and soon, in many other countries for many years to come.

Our flu vaccine candidate, mRNA-1010, has demonstrated positive Phase III results, meeting all immunogenicity endpoints in adults, 18 and older. Our flu-plus-COVID combo vaccine candidate, mRNA-1083, has also shown positive results in Phase III, underscoring our ability to innovate and tackle multiple respiratory illnesses effectively.

These achievements highlight the strength of our mRNA platform and our commitment to public health. We are now five out of five vaccines with positive Phase III data, COVID, RSV, flu, next-gen COVID, [mRNA-73] and our flu-plus-COVID combo.

We are very excited about these achievements and are very thankful for our teams. We believe our technology has a potential to significantly reduce the burden of these respiratory diseases globally and saved millions of people around the world and thus impacting millions of families.

Moving to business highlights for Q2. We manufactured the '24, '25 season COVID vaccine targeting both the KP.2 and JN.1 strength of a virus. We are ready to meet the demand of a '24, '25 respiratory season.

In addition to our approval in the US, we are pleased that mRESVIA received a positive opinion from Europe regulatory agency, EMA with CHMP. We are waiting for regulatory approvals in additional countries around the world.

For (inaudible), we recently announced a partnership in the US with BARDA to address H5 influenza virus and future public health spreads. The agreement awarded Moderna $176 million in funding to accelerate the development of mRNA-based pandemic flu vaccines.

Lastly, our Japanese partnership with Mitsubishi Tanabe Pharma Corporation is an important collaboration. With this joint agreement, we will co-promote Moderna respiratory vaccines in Japan, expanding our reach and impact in the Japanese market.

In Q2, our revenues were up $241 million, which continue to reflect the highly seasonal nature of our respiratory vaccine business. The net loss was $1.3 billion. We ended the quarter with $10.8 billion, [mainly] the strong cash and investment position. This robust financial foundation allows us to continue investing in our key programs and initiatives.

Additionally, we continue to make considerable progress in reducing our operating expenses. Compared to Q2 2023, we have decreased our operating expenses by more than $600 million in Q2 2024. This reduction highlights our commitment to operational efficiency and financial discipline.

Before I hand over to Jamey, I want to touch on an announcement we made last week. We are very pleased and proud to welcome David Rubenstein, the Co-Founder and Co-Chairman of the Carlyle Group to Moderna Board starting next week. David has decades of experience investing and growing businesses across a number of industries.

He is also one of the most respected voices globally on matters related to international affairs and public policy. We are very excited to have join us to help us build Moderna to reach to the next level.

With David joining the Board, Stephen Berendsen is stepping down from the Board and I would like to personally thank him for his many contributions during his tenure, including through the pandemic.

We also announced that Bob Langer has informed the Board of the intention to retire from the Board. As one of our co-founder, Bob has made incredible contributions to Moderna and will not be the company we are today without his vision and insights. I am personally very grateful to Bob or coaching and mentoring, especially during the early years of Moderna, whereas experience was so valuable to me.

With that, let me turn to Jamey.

James Mock - *Moderna Inc - Chief Financial Officer*

Thanks, Stéphane, and hello, everyone. Today, I will walk you through our financial performance for the second quarter and also update you on our financial outlook for the remainder of 2024. Let me start with our commercial performance on slide 9.

Net product sales for Q2 were $184 million, down 37% year over year, mainly driven by lower sales volumes of our COVID-19 vaccine in regions outside of the United States compared to the second quarter of 2023 when we fulfilled orders from prior year contracts. Q2 sales were above our guidance of approximately $100 million, primarily due to stronger-than-expected sales in the United States. We recognized sales from a number of other countries, including a small portion of the Brazil contract we announced last quarter.

Year to date, sales were $351 million, down 83% year over year, largely driven by the same Q2 year-over-year trends I just mentioned a moment ago.

Moving to Slide 10. As I just explained that product sales were $184 million, in Q2, we recognized $35 million of licensing revenue, which is included in the other revenue line of $57 million. This revenue comes from a non-exclusive intellectual property out-licensing agreement with a leading pharmaceutical company in Japan announced in our Q1 earnings call. The deal includes an upfront payment and low double-digit royalties on net sales of their COVID-19 product in Japan.

For the second quarter of 2024, our cost of sales was $115 million, which included $10 million of third-party royalties, $55 million related to unutilized manufacturing capacity and wind-down costs, and $14 million of inventory write-offs. This resulted in our cost of sales representing 62% of net product sales.

As a result of our initiative to resize our manufacturing cost structure, cost of sales was down 84% from Q2 last year when cost of sales was 249%. R&D expenses were $1.2 billion in Q2, reflecting a slight increase of $73 million or 6% year over year. We purchased a priority review voucher during the second quarter, which is included in our Q2 results.

With first half R&D spending at $2.3 billion, we are tracking towards the full-year expected spend of approximately $4.5 billion. SG&A expenses for Q2 were $268 million, reflecting a 19% decrease year-over-year. This reduction is a result of our continued strong focus on cost discipline and strategic investments driving productivity on which I will provide additional detail in the upcoming slides.

We reported zero income tax expense for the second quarter of 2024 compared to an income tax benefit of $369 million in the same period last year. The shift is primarily due to the continued application of a valuation allowance on the majority of our deferred tax assets, which we first established in the third quarter of 2023.

Our net loss for the period was $1.3 billion, an improvement from the net loss of $1.4 billion recorded last year. Loss per share was $3.33 compared to a loss of $3.62 in the second quarter of 2023. We ended Q2 with cash and investments totaling $10.8 billion down from $12.2 billion at the end of Q1, primarily due to ongoing research and development expenses and operating activities.

Moving to slide 11 and similar to Q1, I want to provide additional detail on the cost reductions we are driving across the company. You can see in our Q2 results that we had a 19% year-over-year reduction in SG&A spend due to efficiency gains.

One of the main drivers for the year-over-year reduction in SG&A is from our commercial and medical affairs group. Over the past year, we have built our internal capabilities, which has allowed us to drive cost efficiencies by reducing our use of external consultants and other purchase services. We've also been more focused and targeted on how we invest in this area to drive the strongest possible return on investment.

And as the endemic market has been more seasonal, we have shifted more of our commercial spend into the second half of the year. Additionally, our procurement team has successfully driven company-wide cost reductions in the first half of 2024. Their primary focus has been on reducing third-party supplier rates and we have seen strong progress in contract rates for raw materials, components, clinical, travel and consulting services.

We continue to see strong adoption in artificial intelligence by our employees. which will allow us to scale the business in an efficient manner with a digital-first mindset. For example, in the second quarter, our HR team launched benefits and equity GPs. These AI-driven assistants are designed to handle frequently asked questions previously directed to the HR operations team and allow us to scale efficiently.

Overall, we have built a solid foundation and made purposeful investments in people, processes, and technology. We highlighted some of the significant drivers of the 2Q SG&A savings but we are also seeing additional efficiency savings in R&D and manufacturing. I'm very pleased with the cost savings results in the first half of the year and want to thank our Moderna teams.

Now let's turn to our 2024 financial framework on slide 12. We are revising our expectations for 2024 net product sales to a range of $3.0 billion to $3.5 billion. There are three primary drivers for the updated outlook.

First, we are now expecting very low sales in 2024 from EU member states based on recent feedback and discussions with country health officials. Second, in the US, we are seeing increased competitive pressures for our respiratory vaccines. While this has led to a slower RSD ramp than previously anticipated, we continue to believe in mRESVIA's long-term potential.

Third, in the rest of the world, we have provided for the potential risk of revenue deferrals from 2024 into 2025. We remain committed in our attempt to mitigate these risks but believe it's appropriate to adjust our guidance at this time. Finally, this revenue framework assumes a US COVID vaccination rate similar to last season.

Our second half sales mix will be dependent on timing of regulatory approvals across the world and the number of days available in the third quarter to ship. We currently expect a remaining sales split of 40% to 50% in Q3 with the balance in Q4. We expect cost of sales as a percentage of product sales for the full year to be in the range of 40% to 50% based upon our updated sales range.

For R&D, we continue to expect full-year expenses to be approximately $4.5 billion, down from $4.8 billion in 2023. For SG&A, we continue to expect full-year expenses to be approximately $1.3 billion, down from $1.5 billion in 2023.

Note that we expect SG&A to be higher in the second half versus the first half, primarily due to increased commercial activity, but still expect the second half to be down on a year-over-year basis. We continue to expect taxes to be negligible in 2024 and capital expenditures to be approximately $0.9 billion.

Finally, we continue to expect that we will end 2024 with approximately $9 billion in cash. We have made strong progress in improving our working capital management, which is offsetting the change in our product sales outlook.

With that, I will now hand the call over to Stephen.

Stephen Hoge - *Moderna Inc - President*

Thank you, Jamey. Today, I'll review updates from our clinical programs in three of the four development areas in our portfolio. In the second quarter, we had important updates in respiratory vaccines, oncology, and rare diseases.

Starting with respiratory vaccines. We are very pleased by the approval and ACIP recommendation for our RSV vaccine, mRESVIA.

In the US, for all unvaccinated adult, 75 years and older; and in unvaccinated adults, 60 to 74 years of age, wera an increased risk from RSV. This recommendation was the same as for the other two previously approved RSV vaccines. We also recently received a positive CHMP opinion from the European Medicines Agency for mRESVIA. And as Stephane mentioned earlier, we are working towards approvals in additional countries.

Turning to flu. We are in discussions with multiple regulatory authorities and intend to file in 2024. For our next-generation COVID vaccine, mRNA-1083, we announced positive Phase III efficacy results demonstrating non-inferior efficacy against COVID-19 compared to SPIKEVAX in all trial participants, 12 years of age and older. Efficacy was higher than SPIKEVAX in adults 18 years and older.

We are excited by the data and are sharing the results with regulators and intend to file for approval beginning in 2024.

Rounding out the news and respiratory vaccines development. In the quarter, we shared positive results from our Phase III trial with our combination flu and COVID vaccine. The trial met its primary immunogenicity endpoints with the combination vaccine eliciting higher immune responses against flu and Sars-CoV-2 than the licensed flu and licensed co-vaccine, given separately in adults 50 years of age and older in the trial.

In the subset of participants 65 years of age and older, our combination of vaccine also elicits higher immune responses than an enhanced flu vaccine that is recommended in the 65 and older age group in many countries, including the United States. These results are exciting, and we have begun sharing them with regulators and planning for the next steps.

Turning now to oncology. In the quarter, we shared an update on our mRNA-4157 program, also known as INT, which elicits antitumor T cell responses by targeting a patient's unique tumor mutations or neoantigens.

INT is in multiple large, randomized trials, including two Phase III trials, one in adjuvant melanoma and the other adjuvant non-small cell lung cancer; one Phase II/III trial in adjuvant cutaneous squamous cell carcinoma; and two randomized Phase II studies, one in adjuvant kidney cancer and the other in bladder cancer. We and our partner, Merck, expect to start additional studies in new tumor types.

The development program has launched on the back -- was launched on the back of impressive randomized Phase II trial results in adjuvant melanoma. We recently shared the three-year follow-up data from that trial at ASCO this past June. And on the next few slides, I will quickly summarize the highlights from that presentation.

The primary clinical endpoint for the Phase II adjuvant melanoma study is recurrence-free survival or RFS. As presented at ASCO, there is a sustained improvement in RFS with the combination of INT plus KEYTRUDA versus KEYTRUDA alone through three years of follow-up.

74.8% of patients receiving the combination treatment of IT plus KEYTRUDA world live and tumor-free at three years, which was 19 percentage points higher than KEYTRUDA alone, and resulted in an impressive hazard ratio of plus 0.51.

The combination of INT plus KEYTRUDA also showed sustained improvement in distant metastasis-free survival at three years. 89.3% of patients in combination INT plus KEYTRUDA treatment group were alive and without metastases or distance spread of their tumor at three years of follow-up versus 68.7% of patients in the KEYTRUDA monotherapy group. This is an equally impressive and remarkable hazard ratio of 0.38.

We were lastly pleased to share data showing that an early favorable trend in overall survival at three years of follow-up.

Now finally, on the safety side, INT continues to demonstrate a remarkable profile for our novel cancer therapy. Immune-related adverse events were not [found] in the combination INTs plus KEYTRUDA arm despite the benefits than in the KEYTRUDA monotherapy arm. This highlights the impressive emerging benefit risk profile for our INT program.

Moving now to rare diseases. I'm happy to share that our MMA-candidate mRNA-3705 was selected for the FDA STAR program. M&A is a rare disease in which patients cannot properly break down proteins from the food and digest. As a result, toxins build up in the bloodstream and cause recurrent episodes of life-threatening metabolic decompensation.

The FDA START program is a program designed to accelerate development of new and promising therapies in rare diseases, where there is a high unmet need. Our MMA candidate, mRNA-3705, is being evaluated in patients in a Phase I/II study with encouraging early results that we've previously shared. And we look forward to working with the FDA to accelerate the development of this promising potential medicine.

With that, I'll now turn it back to Stephane.

Stephane Bancel - *Moderna Inc - CEO*

Thank you, Stephen and Jamey. Let's start with COVID -- with the start of the COVID season only a few weeks away, contracting for the season is almost completed as we speak. In the US, we have seen increased competitive pressure during the contracting season compared to last year, and we have not finalized most of the contracts. We are working closely with public officials, healthcare providers, pharmacies to drive vaccination rates. Our collaborative efforts with these stakeholders are critical in driving widespread taxation adoption.

In the EU, we're in advanced discussions on the tender framework to provide market access. However, based on recent feedback from several large governments, we are now expecting variable sales to EU member states in 2024. Some large countries will not buy SPIKEVAX for '24, 25 season.

In the rest of the world, we have multiple signed contracts in place, some of which could be deferred into 2025. Contracting discussions are ongoing with some additional countries, but we do not expect this to have a significant impact on an updated sales framework.

Moving now to the launch preparation for the '24, '25 season. Our organization is fully prepared for the upcoming season, thanks to a substantial effort made by the Moderna teams to ensure the global availability of COVID vaccine.

In North America, we are ready to supply SPIKEVAX targeting KP.2 strain, advised by the FDA, demonstrating our ability to quickly develop and manufacture SPIKEVAX for selected strengths. In the rest of the world, we are supplying vaccine targeting the JN.1 strain as requested by [regulators] in those regions.

Let me now take you through details on the US COVID market. We'll be ready to supply millions of doses to all segments of the US market upon regulatory approval. Our goal is to ensure that SPIKEVAX is available to all customers, larger pharmacies, independent pharmacies, healthcare professionals, IDN hospital network, public health entities at the same time, facilitating early in widespread vaccination. Securing the wider system to be ready to vaccinate is a key priority for us this season.

To that line, we have implemented a real-time order tracking system which is available to all of our customers and provide detailed information on every order, including real timing, package size, and temperature status.

Our supply chain are using AI tools to help estimate the optimal order of distribution to locations within the US market. These preparations highlight our commitment to ensuring the broad availability of buybacks and meeting market demand.

Let me now turn to our marketing efforts. We believe education and awareness campaigns will be important drivers to increase vaccination rates. We have started these efforts early. For end of the season, we have launched a back-to-basics campaign. This initiative is designed to raise awareness about how the SARS-CoV-2 works and why it is critical to get a new booster each year like for flu.

The virus could change over time, and we need to have a new tool to boost our immune system, the new mutations to reduce infection, reduce hospitalization, and reduce deaths. Additionally, we are working with public care authorities to educate the public on the impact of long COVID, highlighting how vaccine can help reduce risk for young and middle-aged adults.

Soon, we will start our in-season outreach to high-risk groups. By collaborating with major retail pharmacies, we aim to effectively market our products during the season. This targeted approach ensures that our efforts are focused on those who are the most vulnerable, maximizing the benefits of vaccination for those groups. By leveraging major channels, we aim to reach a broader audience and emphasize the critical need for vaccination to mitigate severe outcomes.

Let me now turn to our RSV launch. We are very excited about the launch of our second product, mRESVIA. Following the approval, the ACIP vaccine recommendation on par with competitor vaccines. Specifically, ACIP recommended a single dose of RSV vaccine for all unvaccinated adults, age 75 and above. ACIP has commodity a single dose for unpainted adults between the age of 60 and 74, who are at an increased risk.

Based on this recommendation, approximately 40 million people in the US are eligible for vaccination. The RV market size beyond the '24, '25 season will depend on the revaccination recommendation, which are anticipated to be discussed by ACIP in future meetings.

In RSV, our focus into direct our efforts to the segments with the vast majority of our vaccinations occur. In the US, we are targeting the pharmacy segment, which includes both large retail chains as well as independent pharmacies. Together, total pharmacy segment accounted last year for around 95% of our RSV vaccine administration.

We began shipping products in pharmacy in July. And as Jamey mentioned earlier, we are seeing a highly competitive environment. Additionally, larger competitor contracts were negotiated prior to our approval and launch, resulting in lower 2024 share than we would have liked.

Long term, we continue to believe our [PFS propagation] will resonate well with customers, offering them the ability to use the time, much more efficiently during the busy fall vaccination season and to reduce potential medical errors. We look forward to some major upcoming milestones in the near term.

In respiratory vaccine, we expect a COVID approval, and we'll be ready to ship in the US and rest of the world in the August, September time frame. In RSV, we expect to release Phase III data for high-risk individuals, 18 years of age and above. We are in discussion with regulators on our [two] program and intent to file in 2024. We also expect to present immunogenicity data in other adults for flu vaccine versus (inaudible).

For next-gen COVID vaccine, mRNA-1083, we're engaging with regulators and incentive file in 2024. And combination of Flu-COVID vaccine, mRNA-1083, we're engaging regulators and also be able to give an update soon. With this vaccine with CMV fully enrolled and accruing cases, we look forward to potentially Phase III vaccine efficacy readout in 2024.

And as Stephen just talked about, we are very excited about our INT program while looking forward to the completion of the element of a Phase III in adjuvant melanoma, which is, of course, a major milestone.

We are keen to discuss regulators the possibility of accelerated approval based on the Phase II study data. As we shared before, there are three things with you as necessary before we could consider pursuing access of approval for INT. First, durability of data, which we believe that, as Stephen presented, we are there. Second, a substantially enrolled Phase III adjuvant melanoma study. And third, manufacturing readiness at our Marlborough site.

Lastly, in our rare disease portfolio, we look forward to initiating pivotal study for PA and MMA. We're eager to achieve these milestones and to continue to progress towards our mission to deliver the greatest possible impact to people for MRM medicine.

We expect these new some events, combined with further advancement in our pipeline with confirmed power of our platform and its potential to serve patients for years to go. An important save-the-date for your calendar, our annual R&D Day will be held the morning of September 12 in New York City. Of course, webcast will also be available.

Thank you for listening to the call. And we would like now with the team to take your questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Salveen Richter, Goldman Sachs.

Salveen Richter - *Goldman Sachs - Analyst*

A couple for me here. Can you help us understand the factors contributing to maintenance of the year-end cash balance guidance following the lowered product revenue guidance range? And then with regard to competitive pressures noted regarding contracts for COVID into second half, can you be more specific on the factors here, whether it's contracting logistics or the clinical profile, competitive dynamics or what that might be? And third, how much visibility do you have on second half demand for the RSV vaccine based on contracting to date?

James Mock - *Moderna Inc - Chief Financial Officer*

Yeah. So hi, Salveen, I'll take the first question regarding the year-end cash balance. So I would say there's a few factors in there. Number one, on the deferrals of revenue, some of which we have already collected the cash and ultimately, we will collect the remaining balance that might push into 2025, but some of that is already a prepayment.

Number two, as I mentioned in my prepared remarks, we have been working on working capital. We've got a whole team focused on it, and the teams are doing a great job from accounts payable, inventory balances, receivables and our collections progress, you can see our receivables balance on the balance sheet is relatively small at this point. So the team is doing a great job, which helps offset it.

And then third, just coming into the year, we had a little bit of cushion to the $9 billion. So overall, we remain confident in the $9 billion and are pleased with that kind of ending balance heading into 2025.

Stephane Bancel - *Moderna Inc - CEO*

And Salveen, I'll take the two other questions. It's Stephane. On the competitive pressure, I think on both products, COVID and RSV, we are seeing similar things, which is bundling from larger competitors with portfolio of products. [Inability], if you want to also be much more aggressive on activity with various supply chain, average pricing, wherever it's core marketing funding and all those activities.

So it's really a mix of the customer-to-customer level. We've just seen a much more intensive pressure of COVID versus last year.

And on INT, as you know, we're entering the market where there's two large establish player, one with very large market share. We, of course, is trying to defend it. The other one who has indicated they want to gain market share because they are not pleased with market share last year. And so we have been working really actively on that.

In terms of visibility for RSV. We have some contracts that have already been signed and that we are actively supplying customers now that the product is shipped. There are some contracts that are being finalized with ability in season to demonstrate to the customer the value of PFS and to be able to move that into season.

So we're working through all those things. We'll provide updates as the season goes, but we don't think it is very important for patients. It's very important for the company. So we are all hands on deck on COVID and RSV.

Operator

Terence Flynn, Morgan Stanley.

Terrence Flynn - *Morgan Stanley - Analyst*

Maybe two for me as well. I was just wondering on the guidance cut, if you can quantify how much was from COVID versus RSV? And then on the seasonal flu and the seasonal-flu-plus-COVID combo -- might be parsing words here, but on seasonal flu, I noticed the press release that intend to file in 2024, the combos that are engaging with regulators on next steps. So maybe you could just help us think through kind of the gating factors for each of those in the difference in language there.

James Mock - *Moderna Inc - Chief Financial Officer*

Yes. Thanks, Terrence. I'll take the first one related to guidance. And what's the split between COVID and RSV. So what I would say is if you look at the three drivers, all of them are first, similar in size. And then if I break them down, the deferrals are all related to COVID. The EU is all related to COVID. And then that last category of competitiveness in RSV vaccine or respiratory vaccines is a split between COVID and RSV. So that should give you some understanding of the general split between COVID and RSV.

Stephen Hoge - *Moderna Inc - President*

Great. And for the question on the language, good pickup. So the 1083 flu coving program is the most recent Phase III results, really quite fresh. And we have just begun the process of engaging with regulators, meaning sharing that data and discussing with them what their expectations would be on submission.

For the other programs that you referenced, obviously, have more time. Had some of those discussions, and we're obviously preparing for submissions as we said in our prepared remarks.

Operator

Michael Yee, Jefferies.

Michael Yee - *Jefferies - Analyst*

Two questions from us. Looking forward on guidance, you obviously have revenue guidance this year. You have OpEx guidance, which we see is around $6 billion of R&D and SG&A. And as you project out to the following years, you have already given cash flow guidance.

So if things are generally staying along the same trajectory, I would think that cash guidance would be lower. Can you speak to the math there? And perhaps, Jamey, who has said you could flex OpEx, is that of heightened importance and heightened priority more aggressively as you think about where things stand today and the change in guidance and talk to that given cash guidance has been a concern for investors?

The second question is going back to RSV. I appreciate the comments you just said, that was super helpful in breaking it down. Is that to say that the RSV projections you have are going to be perhaps in half? And is that due to lower share or lower price, and speak to that?

James Mock - *Moderna Inc - Chief Financial Officer*

Yeah. Thanks, Mike. So we are still -- as I mentioned, we're still expecting $9 billion in cash next year and don't currently have any different change in our outlook for the $6 billion to $7 billion that we said we'd end in 2025 with, and let me break that down.

So first, this year, we went from the start of the year, $13 billion to $9 billion, so a $4 billion loss in cash. That included many pre-payments coming into the year that will no longer repeat. So we're not actually getting the cash from operations, and that won't be a drag year over year.

Second, we plan to return to growth in 2025. And as I mentioned earlier, some of that will also be moved by the fact that we have some deferrals heading into 2025. But more so, we'll have an entire year and operating experience on RSV, we hope to bring new products to market, and so we're still expecting to return to growth.

But yes, I mean, we continue to look at OpEx and understand what we want to do there, and we are always laser-focused on our cash balance. And at this time, we don't think the $6 billion to $7 billion will change.

Michael Yee - *Jefferies - Analyst*

Okay. And then on to be breaking it down, just a little more specifics, on the impact of market share contracting and price and how to think about that.

James Mock - *Moderna Inc - Chief Financial Officer*

Yah, a bit of both. We're not breaking it down nor have we given guidance on RSV. But I would say this year is not turning out as we expected. And I answered Terrence questions in terms of how much is really split between COVID and RSV, so you can kind of get an understanding there.

But again, we were third to market this year. Some of the contracts were already negotiated. We only are participating in the second half. But I think our hope is that we get access across many of the retail chains. We started to us to get comfortable with us with a second product. So that when we head into 2025, we can get a more fairer market share on RSV.

Operator

Eliana Merle, UBS.

Elliott Bosco - *UBS - Analyst*

This is Elliott Bosco from UBS on for Ellie Merle. Two from us. Can you elaborate on the latest timing you expect for the Phase III CMV study based on how event rates are tracking? And based on just the necessary 12 months of median safety follow-up, from a purely protocol perspective, what is the earliest we could potentially get the interim?

And then second, on international COVID revenues in future years. What do you see is the likelihood of potential deferral again in 2025?

Stephen Hoge - *Moderna Inc - President*

Great. Thanks for the question. I'll take the first. So first, we have an update on case numbers for CMV. We may have enough at R&D Day, I'm not sure. But we don't have any change to our prior guidance, which is we do think that the interim analysis of efficacy could happen this year. And that would account for also a median safety follow-up from a timing perspective.

And so at this point, no new update, but we continue to stand to believe that the interim analysis for [FCM] the CMV program could happen this year.

James Mock - *Moderna Inc - Chief Financial Officer*

Yeah. And Elliott, on the deferrals, could they happen in 2025? The answer is yes, they can always happen. That said, some of this will push into next year. So -- and if some of those push into the following year, those two would offset we're not expecting that at that point.

The other thing I'd say is we will come to market with our resilience contracts in the UK, Australia and Canada. That provides us an additional growth in those areas as well as potentially participating in additional public tenders as well. So there's a little bit of risk, but I think we can mitigate it with the deferrals from this year as well as additional resilience contracts.

Operator

Gena Wang, Barclays.

Gena Wang - *Barclays - Analyst*

I just have one question regarding the guidance for this year, particularly regarding the COVID revenue in the US. And the since contracting is mostly down and you already also expect similar vaccination way versus the last year. And we know there is mainly only two players. So what could lead to the lower COVID revenue this year from prior $2 billion guidance.

James Mock - *Moderna Inc - Chief Financial Officer*

Yeah. Thanks, Gena. So we define competitiveness, both in terms of share and in price. So we're relatively pleased with our market share. There's potentially some price pressure in there.

But generally speaking, we think that the US will perform pretty well compared to last year. But we are seeing a bit of a competitive -- a more competitive market this year. After a year where in the US, we had nearly 50% or approximately 50% market share. So we're seeing the pressure, but still confident in the overall performance of the US business.

Operator

Luca Issi, RBC Capital.

Luca Issi - *RBC - Analyst*

Maybe, Stephen, quick question on the recent ACIP meeting. If you estimated the debate before that ASIC meeting was whether RSV was going to be either annual or every other year vaccine. However, ACIP clearly chose a meter of them and simply said, this is one and done. So two questions.

Were you surprised by that decision? And two, how should we think about the market potential for RSV long term in light of the fact and this is maybe one and done vaccine versus obviously COVID and flu our annual vaccines. Any color there much appreciated. And then maybe quick can me walk us through what the latest thinking on the opportunity for bird flu.

Stephen Hoge - *Moderna Inc - President*

Great. Thank you for both questions. So obviously, first and foremost, our focus at the ACIP meeting was we're quite pleased with the parity recommendation.

And I think we're all pleased with the clear recommendation for those over the age of 75 and those with higher risk from RP that they really should get back to noon. As it's only a year old as a market, the most important thing we can do is cover the large number of people who are now recommended 40 million-plus who are not vaccinated and that's a quite large increase in the number of folks who we hope to cover soon.

Now on the question to your specific question of revaccination. I think it's also important to say that we are -- the ACIP is really just looking at one year of real-world data. And all three of the vaccines, but including mRESVIA, show significant second season protection although it does decrease.

And so there is a decline from season one into season two from a clinical trial perspective, but there's still protection there in that year, too. And so while you're only one year into that public experience, public health experience, I think ACIP took a prudent choice and said there's still a benefit and maybe the focus should be on increasing vaccination coverage rates for those who are currently unprotected because there clearly is some benefit, even still out that second year.

I think if you fast forward a year, and this would be my perception. But if you fast forward a year, if you look at the rates of waning for the other two vaccines and ours, there's clearly a decline from year one to two and from your two to three and the pace of that decline suggests that by year three, there really won't be much protection for those people who have received vaccines in the first year. I think that's when you probably need to start asking a question of do we continue to leave those people unprotected or boost them again.

Now from a scientific perspective, you asked my view, you will be infected with RSV doesn't almost 20 times in your life. You will repeatedly get ill. In fact, many people who are at risk of severe complications over the age of 75 or other lines with medical comorbidity, they see RSV before. It's the waning protection from that infection that ultimately is the reason why you need a vaccine.

And because you get infected multiple times by that virus over their life, even if you've seen it before, you probably will benefit from a booster in the future. And so we continue to believe that as the public health story evolves, that recommending bodies in CDC and ACIP will look at the waning efficacy, the potential to boost people again and hopefully provide additional public benefit. And that eventually, there will be recommendations for revaccination for those who are at highest risk of RSV.

But it is not our choice at all, because we are providing that data to, obviously, the regulator but principally to groups like CDC now, and then they will determine the right moment, if ever, to recommend that revaccination in the United States.

As it relates to bird flu, we continue to follow that very quickly, that drifted a little bit out of the news more recently. I think that's a good thing. But the most important news for us has been in the quarter, we excluded an agreement with BARDA to advance into Phase III with our pandemic bird flu vaccine, which we'll provide updates on as we move forward in the months and the year ahead.

But we will be sure to be partnering with public health entities across the world, including the United States government, specifically are grateful for working with BARDA again, in the event that Burcu does emerge as a pandemic epidemic through this country.

Operator

Alexandra Hamman, BofA.

Alexandra Hamman - *Bank of America Merrill Lynch - Analyst*

So how do results for [BS522] in collaboration for [KEYTRUDA] as results provide positive proof of concept for the ability of mRNA and liponanoparticles to be artilized and cross the newer in the lung. Can you walk us through additional indications you may be interested in? And should we expect you to develop these indications in partnership with Vertex?

Stephen Hoge - *Moderna Inc - President*

Thanks for the question. So -- we have -- as you highlighted, there was a large number of pulmonary diseases for which respiratory delivery could be quite impactful. We have not provided any updates on the preclinical programs that we've moved into development.

And so I would describe those activities right now as still research and discovery phase and therefore not something for competitive reasons and precise agreement that we'll talk about. They're in the earlier stages.

As it relates to whether we would partner with Vertex, we would, of course, always be welcome -- we welcome partnering with Vertex given their expertise. But the partnership we have right now, the deal we have with them is limited to the cystic fibrosis program at this point.

Operator

Edward Tenthoff, Piper Sandler.

Edward Tenthoff - *Piper Sandler - Analyst*

Most of my questions have been answered. I appreciate all the detail. I wanted to ask a little bit about the orphan disease programs. So maybe you can provide a little bit of color on what the regulatory path might look like in MMA and PA.

Stephen Hoge - *Moderna Inc - President*

Thanks, Ed. So they are somewhat different and they are early stages of those regulatory conversations. So we just received the FDA Start designation.

But if you look at the data that we shared last R&D Day, and we'll obviously provide updates on this going forward, one of the clearer pictures that emerged was that in MMA, we are seeing good movement of a biomarker, metamolonic acid, that's pathognomonic for the disease. And so you can imagine one of the challenges very quickly when you have a good biomarker.

It's how do you validate that biomarker and show that moving that biomarker is reasonably likely to predict and that's a scientific question we will work on and ultimately engage with regulators, including FDA on as a key step for moving forward. We are evaluating in the clinical trial folks and their movement in their biomarker from baseline. So it's a clear study to run.

In the case of propionic acidemia, there is not as clear a biomarker in the field because of the structure of that particular part of the metabolic pathway.

And so there, we've been following events. And as you know, we previously shared in a single-arm study, the pre and post-treatment rates of metabolic compensations. We have seen a favorable trend in that. We're actually quite excited about that.

That takes a little more time than biomarker, but we obviously have been working on that a little bit longer. And so we'll be engaging with regulators on that single-arm approach and understanding the difference between internal controls or other control groups to evaluate that.

In any event, you may end up with a randomized study, you may be able to use a single-arm study. And in the case of you may or may not be able to use the biomarker. So those are the kinds of conversations that we're having. But as I said, they're early days. The FDA start discussion on M&A just started. And so we'll provide updates as we have more clarity on those times.

Operator

Jessica Fye, JPMorgan.

Jessica Fye - *JPMorgan - Analyst*

For RSV, I'm curious your take on Pfizer's comment that customers want to carry an RSV vaccine that can address both the maternal and the older adult population.

And then for INT I saw on the near-term milestone slide. But to clarify, what's your latest projection on when you expect to complete enrollment of the Phase III adjuvant melanoma trial? And what's the latest you can share on manufacturing progress for that product? Are there any updates to share on how that's going?

Stephen Hoge - *Moderna Inc - President*

(multiple speakers)

Obviously, the majority of the recommended population in this country continues to be the older adults. I wouldn't comment on Pfizer's competitive positioning on their quarterly call, except to say that in the retail channel, overwhelmingly and in many physician offices, overwhelmingly, the focus is on protecting older Americans. What's happening with a younger population, maternal population is obviously smaller in terms of an overall market opportunity.

We do recognize the need to try and provide the broadest potential label and as we previously updated, we are pleased that we've conducted our Phase III study in 18 to 59-year-old high-risk population, and we intend to file that this year with the goal of expanding that label for those who are at high risk for medical and may benefit from an RSV vaccine even if they are younger.

And so I would say we agree that a broad label is valuable, but I think it's important to cover as many people as possible, and that's where we're excited by moving forward with our 18 to 59-year-old filing.

On the question of INT, we're -- we have not, with our partner, updated yet on where we are in enrollment. Obviously, as we had said at ASCO, and there was quite some coverage of, it's been brisk. We are pleased, very pleased with the pace of enrollment. And we do expect that to conclude quickly, but we have not yet provided any updates and we'll obviously do so at the appropriate time with our partner, Merck.

As it relates to manufacturing, we actually have made great progress there of establishing our Marlboro facility as well as demonstrating through the clinical trial, our ability to manufacture at high volume, frankly, commercially relevant volumes.

And so we're we feel like we're in a good place in terms of the manufacturing trajectory. It's still a few months of work to go this year to get to where we want to be, but we're starting to feel quite optimistic that the manufacturing will be online as and when we hope.

Operator

[Evan Wang], Guggenheim Securities.

Unidentified Participant 1

A few for me. Just first, just given all the comments on the higher competitive environment, how are you thinking longer term about the outlook for RSV and COVID versus some of the assets you made earlier in the year and historically, just given some of the pricing and market share dynamics there.

Second, with COVID in the EU tender, what's your level of confidence in the EU being a meaningful contributor in -- and what changes between now and then? Does having the combo or potentially having a combo add to competitiveness there?

And lastly, I saw that you guys purchased a PRV, is that for use on the combo or the standalone flu -- and are you comfortable in getting ahead of a potential June recommendation next year?

Stephane Bancel - *Moderna Inc - CEO*

Thanks. This is Stéphane. So on the higher competitive environment on COVID-19. What we believe is on ISV as customers are going to experience the PFS product, and that will have the ability to really have kind of flu season to be able to train and to get the products through the channel that will help a lot. So we anticipate in '25 to a better share than in '24 for the US. So we're going to be launching all the outside US markets in '25, but of course, will not have sales in '24, that's going to be important for growth.

In COVID, we believe the portfolio in terms of next-gen COVID and flu plus COVID. These are important to drivers to kind of reset the expectation moving forward and the market dynamics.

In terms of the EU, the current contract between Pfizer and EU end in 2026. So we think 2025 and 2026 are still going to be low. Some countries have actually used a lot of air vaccines. And so we could see some countries in '25 and more '26 needing COVID vaccine and then wanting to diversify their supply base.

We our vaccine as well given its performance. First, as you mentioned, the combo is something that we have been discussing quite a lot with governments in Europe basically the value of a combo given its strong performance as we've shared to be an important tool for public health in terms of compliance in a world where governments are worried about people getting their flu shots and the COVID shots and the RSV shots, there just a lot of shots and nobody likes needle, so we like to go to the doctors and to the pharmacies.

And so the combo is something that the customers are really valuing. And so that could be another opportunity in countries when this product is available to go back into growing Europe. The key priority for us in Europe now for 2025 is really launching RSV and growing the business around RSV until we see the flu model or a flu plus COVID launch.

Operator

Tyler Van Buren, TD Securities.

Unidentified Participant 2

This is [Greg] on behalf of Tyler from TD Securities. So I understand your thoughts on the magnitude of the RSV market, (technical difficulty) being small relative to last year during the earnings, so you agree? And what is your latest thinking on the overall size of the RSV market in elderly patients versus the prior, or they built in expectations?

Lavina Talukdar - *Moderna Inc - IR*

So you broke up a little bit during your question. I think the -- we caught the tail end of your question, which is what is the size of the RSV market relative to what we thought previously.

Unidentified Participant 2

Yes. Thank you. So just to reiterate quickly, I believe that GSK discussed RSV market being smaller business relative to last year's earnings call (technical difficulty) what was your latest thinking on the overall size versus the prior $6 billion to $8 billion (technical difficulty)

Stephane Bancel - *Moderna Inc - CEO*

Yeah. So let me try to take a stab at it. As Stephen said, in the long term, we believe that as real all evidence data is gathered by public health leaders, that they will most probably be a need for boosting. The current organization is what it is. But as Stephen said, we believe this will potentially evolve over time.

For this year, I think what is interesting is on paper, it seems that it could be a smaller market. The thing that's going be interesting to see how it plays out in terms of market size and number of doses in arms is the guidelines are much more clear than last year. And as you know, sometimes in vaccinations, you get a better reaction from the doctors and pharmacies and consumer with clear guidelines versus not as guidelines with a larger population potential.

So because of those two factors, it's going to be interesting to see how the season plays out.

Stephen Hoge - *Moderna Inc - President*

I would just comment on the current year market size as well. I think we've talked about what we believe the patient population is, which is still sizable. And we believe that the market will still be overall sizable this year and similar to last year, a little bit more.

And I think there are other factors at play with those comments. There was a lot of inventory that was -- or a lot of sales that happened in the prior year that customers may be sitting on some of that inventory. So from a revenue perspective, that might be different. But from a vaccination rate perspective, we believe that it will still be similar, if not a little bit bigger this year.

Operator

Cory Kasimov, Evercore.

Unidentified Participant 3

This is [Adi] on for Cory. Another question on -- has the recent summer coveted caused any concern for fall vaccination as the infected population is usually recommended not to get vaccinated for six months post infection? And is the base case for the US COVID revenue is similar vaccination as last year which I think our CDC tracking was 22.5% overall population, 40% for 65 and above.

Stephen Hoge - *Moderna Inc - President*

Yeah, I'll take it. So first, the question on the summer wave in the epidemiology. We've seen this multiple years in a row now. And so in some ways, there is move in certain geographies towards a little bit of a summer wave.

It just highlights the fact that this virus is incredibly effective at spreading, incredibly effective at creating disease even for folks many years after vaccination and other protection and why we need to protect people for the winter season because the whatever we see in the summer, you see a dramatically higher rate in the November through February time. And so that's really where we're trying to protect people for.

But in terms of business, summer wave impact, the small summer wave impact the view of the fall wave, it really doesn't change year-over-year that perspective. And that's why we're confident the vaccination coverage rate will still be there. And as Jamey said, we see them the same. We hope to do better, but we see them minimally as similar to last year in the United States.

Operator

Thank you. Ladies and gentlemen, this does conclude the Q&A portion of today's call. I'd like to turn it back to Stéphane Bancel for any closing remarks.

Stephane Bancel - *Moderna Inc - CEO*

Well, thank you, everybody, for joining us, and we look forward to speaking to many of you in the coming days and weeks and if not seeing you for R&D day in September 2. Have a great day. Bye.

Operator

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