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MRNA.OQ - Q2 2025 Moderna Inc Earnings Call

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OVERVIEW:

Company Summary

REFINITIV

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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to Moderna's second quarter 2025 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, Head of IR. Please go ahead.

Lavina Talukdar - *Moderna Inc - Head - Investor Relations*

Thank you, Kevin. Good morning, and good afternoon, everyone. Thank you for joining today's call to discuss Moderna's second quarter 2025 financial results and business update. You can access the press release issued this morning as well as the slides that we'll be reviewing by going to the Investors section of our website. On today's call are Stephane Bancel, our Chief Executive Officer; 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 now turn it over to Stephane.

Stephane Bancel - *Moderna Inc - Chief Executive Officer, Director*

Thank you, Lavina. Good morning, or good afternoon, everyone. Thank you for joining us today. I will start with a quick review of Q2. Jamey will present our financial results and outlook. Stephen will review our clinical programs, and then I will come back and share our key priorities and catalysts before we take your questions.

Let me start with a review of our financials. In the second quarter, our revenues of $0.1 billion and a loss of $0.8 billion were in line with our expectations, and they reflect the highly seasonal nature of our Respiratory Vaccine business.

We ended the quarter with $7.5 billion in cash and investments. We remain highly focused on financial discipline. I'm very pleased to announce that continued cost reduction efforts across the company in the second quarter of 2025 led to a 35% reduction of cost of sales, R&D, and SG&A combined, compared to the second quarter of 2024. As you know, we are very focused on cash cost, and I'm happy to report that on a cash cost basis, we reduced operating expenses by $581 million in Q2 2025 versus Q2 2024, which is a 40% reduction year over year.

During the quarter, we made solid progress across our three strategic priorities. Priority one, driving use of our commercial products. We made strong progress in securing three approvals from the US FDA. On May 31, we were very pleased to announce the FDA approval of mNEXSPIKE, our next-generation COVID vaccine that has shown even higher efficacy than our Spikevax vaccine. In mid-June, we received FDA approval of our mRESVIA vaccine for high-risk individual aged 18 to 59.

As a reminder, we are also approved for adults 60 and older in the US and in 38 other countries. And in July, the FDA granted full approval of our Spikevax COVID vaccine for high-risk children aged 6 months through 11 years. This vaccine has previously been used under EUA. These approvals support our broader goal of driving use of our commercial products and driving the company back into sales growth.

On our second priority, advancing our pipeline to drive sales growth. We are very happy to announce positive and strong Phase III efficacy data for flu, which we believe will advance both our flu program and our flu plus COVID combination program. Stephen will discuss these results shortly.

And our third priority, executing with financial discipline. The second quarter 2025 marked the fourth consecutive quarter where we've reduced combined R&D and SG&A expenses by double digits year over year. Additionally, in the second quarter, we expanded our cost reduction plan well beyond what we announced in the first quarter. We estimate that these measures will take an additional $400 million out of 2025 cost structure we previously laid out. This cost reduction includes a very difficult decision that we announced yesterday to reduce headcount by around 10% to better align Moderna cost structure and capabilities with current business conditions while also sustaining investments in our mRNA pipeline.

This decision was obviously not made lightly. It impacts people who have dedicated themselves to our mission, teammates, and friends who have built Moderna. I want to express, on behalf of the entire executive committee, our deepest thanks to all of those affected for what they have contributed to the company. These colleagues will always be part of the Moderna story.

Finally, before I hand to Jamey, you may have seen that in the last couple of hours, the UK Court of Appeal issued its decision. The court has decided to uphold the High Court's finding that Moderna's EP'949 patent is valid and infringed by Pfizer and BioNTech. Moderna will continue to pursue and enforce its patent rights globally to protect its innovative mRNA technology. Jamey?

James Mock - *Moderna Inc - Chief Financial Officer*

Thanks, Stephane, and hello, everyone. Today, I'll cover our second-quarter financial results, our updated 2025 full-year outlook, and share our strategy to achieve our 2027 operating cost targets. Let's begin with our second-quarter financial results on slide 7. Net product sales were $114 million, primarily driven by COVID vaccine sales. The US accounted for approximately 80% of sales this quarter with the remainder from international markets. While product sales declined 38% compared to the second quarter of 2024, sales were slightly above our expectations due to a stronger-than-expected US spring booster season.

We also recorded $28 million in other revenue, bringing total revenue to the quarter to $142 million. The year-over-year decline in other revenue was primarily driven by a $30 million upfront licensing payment that was recognized in the second quarter of last year. Cost of sales for the quarter was $119 million, which was relatively flat compared to $115 million last year. It represented 105% of net product sales this quarter, up from 62% in the prior year, driven primarily by lower volume.

R&D expenses were $700 million in the second quarter, down 43% from last year. The decline was primarily driven by the wind down of our respiratory trials and lower clinical manufacturing costs. We also had year-over-year reductions in preclinical and external service costs, reflecting

ongoing portfolio prioritization and productivity efforts. Last year's results also included an expense for a priority review voucher. SG&A expenses were $230 million for the quarter, down 14% year over year. The decrease reflects broad-based cost reductions across external services, personnel, and commercial activities as we continue to streamline operations and manage expenses with discipline.

Our income tax provision for the quarter was immaterial, consistent with the prior year. We continue to maintain a global valuation allowance against the majority of our deferred tax assets, which limits our ability to recognize tax benefits for the quarter. Net loss for the quarter was $825 million, a $454 million improvement compared to a $1.3 billion loss in the second quarter of 2024. Loss per share was $2.13, an improvement from a loss of $3.33 in 2024. We ended Q2 with cash and investments of $7.5 billion, down from $8.4 billion at the end of Q1. The decrease was primarily driven by the operating loss for the quarter.

Moving to slide 8. I will share our updated 2025 financial framework. For total revenue, we are updating our 2025 projected revenue range to $1.5 billion to $2.2 billion, reflecting a $300 million reduction at the high end. This change is primarily due to a timing shift of UK COVID shipments from the second half of 2025 into the first quarter of 2026. The timing shift for the UK shipments is due to the government's use of their fiscal year minimum purchase -- product purchase for the spring campaign in 2026. So our deliveries will now deliver in 1Q 2026. This represents the vast majority of the $300 million impact. Importantly, the timing shift does not impact the total value of our long-term multiyear contract with the UK government.

Our updated revenue range continues to reflect the uncertainties in vaccination rates, the competitive market environment, the size of the RSV market, and timing of licensure of our factories and product approvals in Australia and Canada. On a geographic basis, we are updating US product sales -- we are expecting US product sales of $1.0 billion to $1.5 billion, international product sales of $0.4 billion to $0.6 billion, and other revenues of approximately $100 million, where the majority is international.

For US product sales of $1.0 billion to $1.5 billion, the high end of the range assumes flat year-over-year performance after adjusting for last year's $200 million prior period return reserve reversal. The low end of the range factors the potential combined impacts from lower vaccination rates and competitive market pressures.

For international product sales of $0.4 billion to $0.6 billion, the low end of the range is mainly from secured contracts, while the high end factors in incremental revenue from active tenders. The net range now also reflects the shift in shipments for the UK from the second half of 2025 to the first quarter of 2026. For other revenues of $100 million, we've already recognized $50 million in the first half of the year and expect a similar amount in the second half. The majority of the revenue is associated with our new manufacturing sites but also includes some grant, collaboration, licensing, and royalty revenue.

The split of our 3Q and 4Q revenue mix will be dependent on timing of regulatory approvals across the world and the number of days available to ship in the third quarter. We expect the revenue split of 40% to 50% in Q3 with the balance in Q4. Our cost of sales estimate of $1.2 billion remains unchanged and reflects year-over-year improvements in manufacturing efficiency, offset by increased costs associated with the go-live of our new international manufacturing sites. Newly introduced tariffs are not expected to have a material impact on our cost of sales. We continue to monitor changes to global tariffs.

We are lowering our R&D expense forecast from $4.1 billion to a range of $3.6 billion to $3.8 billion due to Phase III trial wind-downs, continued portfolio prioritization, and productivity. Our revised R&D guidance projects an increase in the second half versus the first half, driven by the seasonality of vaccine spend as well as studies in support of regulatory approvals.

SG&A expenses are still expected to be $1.1 billion. Similar to last year, we expect higher SG&A expenses in the second half of the year, primarily due to commercial-related activity, but also due to severance charges associated with the workforce reduction we announced yesterday. We expect taxes to be negligible in 2025. Our capital expenditures projection has been lowered from $400 million down to $300 million due to our continued prioritization and efficiency gains. We still expect to end 2025 with approximately $6 billion in cash and investments.

Moving to slide 9. As discussed on last quarter's call, we are planning a total reduction in annual GAAP operating expenses of over $6 billion from $11 billion in 2023 to $5 billion or less in 2027. On a cash cost basis, which excludes stock-based compensation, depreciation, and amortization,

we are decreasing annual operating expenses from $8.9 billion in 2023 to our midpoint target of $4.2 billion in 2027, which is a reduction of over 50%.

Our revised 2025 GAAP operating expense range is now $5.9 billion to $6.1 billion, a $400 million reduction at the midpoint from our previous guidance of $6.4 billion. This updated guidance puts us on track to achieve the first $5 billion of our overall $6 billion reduction in annual GAAP expenses in two years. Our updated 2025 guidance includes $0.9 billion of non-cash expenses from stock-based compensation, depreciation, and amortization. Excluding those non-cash items, we now project a 2025 cash cost of approximately $5.1 billion. At the midpoint of the range, a $400 million reduction from our previous cash cost estimate of $5.5 billion.

The strong progress in cost reductions to date has been a company-wide effort. While we continue to drive additional cost reductions in all areas, the largest source of future reductions will come from R&D, which represents over 60% of our cost base.

On the next slide, I want to share our strategy to achieve our 2027 operating expense targets in more detail. On slide 10, you can see our GAAP and cash cost targets for 2025 versus 2027. At the midpoint of our ranges, we are targeting a $1.1 billion GAAP cost reduction from $6 billion in '25 to $4.9 billion in '27 and a $900 million cash cost reduction from $5.1 billion in '25 to $4.2 billion in '27.

There are four primary drivers to achieve this goal, which are all relatively evenly split in impact. First, a reduction in R&D expenses from the completion of our large Phase III trials. We are already seeing the impact of the completion of most of our respiratory trials in 2025, and we'll start to see future cost savings by 2027 from the completion of our Phase III trials for CMV and norovirus. This includes both direct trial costs as well as reductions in clinical manufacturing and other related overheads. These cost reductions will be partially offset by select investments in the pipeline, such as our oncology portfolio.

Second, we will continue to drive manufacturing efficiencies, which will impact both cost of sales and R&D. We have already made strong progress over the past few years to optimize our manufacturing footprint from endemic level demand of our COVID vaccine. We expect to drive additional savings through process improvements as well as reductions in future inventory write-downs. For example, in 2024, we had $0.5 billion of inventory write-downs, which we are actively driving to reduce in 2025 and beyond.

Third, we continue to drive procurement savings. Some of the savings from the renegotiated contracts already taken place will not be fully realized until 2026. Additionally, we have a strong pipeline of new savings initiatives.

Fourth, we announced a workforce restructuring yesterday that impacts approximately 10% of our employees and will lower our employee base to under 5,000 by the end of the year versus 5,800 at the beginning of the year. Headcount reductions are always difficult decisions as they impact valued colleagues have contributed meaningfully to our mission. However, these actions are necessary to reshape our capabilities and align to our long-term operating cost structure.

In summary, in just two years, the team has made tremendous progress towards our four-year roughly $5 billion cash cost reduction plan. By the end of 2025, we have taken nearly $4 billion of cost out of the business and have an achievable plan to remove another $1 billion over the next two years. We remain committed to breaking even on a cash cost basis in 2028 and will adjust spending as necessary.

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

Stephen Hoge - *Moderna Inc - President*

Thank you, Jamey, and good morning, or good afternoon, everyone. Today, I'll review progress across our pipeline. Slide 12 is a review of our prioritized pipeline. As Stephane stated earlier, we have announced significant updates for many of these programs, including the recent approval for mNEXSPIKE, an expanded label for mRESVIA, and approval of our pediatric Spikevax COVID vaccine, which was previously available in the United States under an emergency use authorization.

In the quarter, we also reported strong vaccine efficacy results from our Phase III seasonal flu trial, and we continue to make progress in the rest of the prioritized portfolio, where we are targeting a total of additional potential filings through 2028.

Moving to slide 13, which outlines the latest developments of our late-stage Respiratory portfolio. I'll start with our COVID vaccine, Spikevax and the mNEXSPIKE. As mentioned earlier, we are very pleased with the FDA's approval of the mNEXSPIKE our next-generation COVID vaccine, which has shown strong relative vaccine efficacy compared to Spikevax in its Phase III trial, including in the 65 and older age subgroup and in those with risk factors for severe COVID-19.

mNEXSPIKE was approved in the US for individuals 65 and older and for people 12 to 64 with at least one risk factor. An extensive analysis of the Phase III clinical data for mNEXSPIKE was published last month in The Lancet, and the link to the publication can be found on this slide.

We submitted the annual updates for our COVID-19 vaccines for the currently recommended LP.8.1 strain in the quarter and expect mNEXSPIKE and Spikevax will be available this fall in the United States. Speaking of Spikevax, the vaccine was recently approved by the FDA for high-risk children ages 6 months to 11 years. Spikevax had previously been available to this age group in the US only under an emergency use authorization. Earlier this week, Spikevax also received EMA approval for the current season update LP.8.1 strain update for the coming season.

For RSV, our mRESVIA vaccine was approved by the FDA on June 12 for individuals ages 18 to 59 with at least one risk factor. The CDC subsequently adopted the ACIP recommendation for the 50- to 59-year old age cohort in this group, which means that recommendations for our vaccine are now consistent with competitors.

For our seasonal flu vaccine, we announced positive results from our Phase III efficacy study. We are very pleased with the results, which I'll talk through on the next slide. We expect these flu results will also support our discussions with regulators about our flu plus COVID combination vaccine, and we have begun consultations with regulators on the submission requirements for both vaccines.

On slide 14, I will discuss the very encouraging P304 flu vaccine efficacy data released during the quarter. In this 40,000-person study conducted across 11 countries, our seasonal flu vaccine, mRNA-1010, demonstrated relative vaccine efficacy that was 26.6% higher than the licensed standard dose comparator in adults aged 50 and above. Safety and tolerability of mRNA-1010 were consistent with previously reported Phase III results, and the majority of solicited adverse reactions were mild.

Importantly, strong relative vaccine efficacy was observed for all three influenza strains contained in the vaccine, including H1N1, H3N2 and the B/Victoria strain. Likewise, the relative vaccine efficacy was consistently strong across age groups, risk factors, and previous vaccination status. In the important 65 and older demographic relative vaccine efficacy was a strong 27.4%.

We look forward to presenting these data at an upcoming medical conference, and we are preparing to file for FDA approval for this vaccine.

Now turning to our Non-respiratory Vaccine and Rare Disease portfolios. In our Phase III CMV efficacy study for mRNA-1647, we have now accrued sufficient primary endpoint cases for the final analysis. The analysis has not yet been conducted, and the company remains fully blinded at this time. We've submitted an amendment to the analysis plan to add important powered secondary endpoints that we hope will increase the scientific value of the results. Once the updated analysis plan is formalized, we will proceed with the analysis of primary and secondary endpoints, which we expect to complete in the fall.

Our Phase III norovirus study is now accruing cases in its first season. As with other studies, the interim analysis of efficacy is dependent on case accrual. And depending upon the rate case accrual, the study has been designed so that it may proceed to a second season of enrollment if necessary.

In Rare Diseases, our propionic acidemia or PA program is currently in a registrational study, and we believe we are on track for a potential 2027 approval. For methylmalonic acidemia, or MMA, we plan to initiate the registrational trial this year.

We continue to advance our Oncology portfolio, with significant progress across our individualized neoantigen therapy, known as Intismeran, mRNA-4359 previously called Checkpoint, and our early-stage oncology pipeline. In collaboration with Merck, we have several late-stage studies underway for Intismeran. As a reminder, the Phase III trial in adjuvant melanoma is fully enrolled and accruing cases towards its interim analysis. Our Phase II adjuvant renal cell carcinoma trial is fully enrolled as well.

And as we have disclosed previously, we have two Phase III studies in non-small cell lung cancer, one Phase II study in high-risk muscle-invasive bladder cancer, and one Phase II study in high-risk non-muscle invasive bladder cancer. We have also expanded our Intismeran program into a Phase II study in first-line metastatic melanoma. This could be the first of many studies using Intismeran and KEYTRUDA together in metastatic indications. Following on from Intismeran, mRNA-4359 is now in a Phase II study in first-line metastatic melanoma and first-line metastatic non-small cell lung cancer. And we are currently enrolling patients in the lung cancer portion of that study.

We are pleased that the data from the Phase Ib study of mRNA-4359 plus KEYTRUDA in Checkpoint inhibitor refractory PD-L1 positive patients was accepted as a mini oral presentation at ESMO. We look forward to presenting these findings at the meeting in October.

In early-stage oncology, we are also dosing patients in our Phase I tumor-targeted antigen therapy, mRNA-4106; and the INDs for our cell therapy enhancing engine therapy, mRNA-4203; and our T cell engager, mRNA-2808 are also now both open. We are pleased by our growing oncology pipeline and the continued strong momentum of the large Intismeran clinical trial program in partnership with Merck.

With that, I'll hand over to Stephane.

Stephane Bancel - *Moderna Inc - Chief Executive Officer, Director*

Thank you, Stephen and Jamey. As you know, we have three priorities: priority one, drive sales of approved products; priority two, focus on our late-stage pipeline, where we can drive product growth for approvals; and priority thee, delivering on our cost efficiency across the company. Our first priorities will drive use of mNEXSPIKE, Spikevax, and mRESVIA vaccines. We entered the third quarter of 2025 with three approved products in the US, and we are seeing a growing number of approvals in countries worldwide.

For priority two, we are focused on delivering up to 10 products approval, which we believe will drive sales growth for the company. Together, these 10 anticipated products target an addressable market that is over $30 billion. In Q2, we secured US approvals for mNEXSPIKE and mRESVIA for (inaudible) people, and which are exciting data in flu, enabling flu and flu-COVID combo.

On the cost side of the house, we've demonstrated our commitment to cost discipline to the reduction achieved in last year in 2024 and also in 2025 to date. We remain confident in our ability to further streamline our operational structure for the remaining of '25 to 2027. CMV just took you through our plans to cut an additional $400 million of our 2025 cost structure, and we are not done. We have many new projects in the works to reduce cost further.

These cost reduction activities we have in place gives us even greater confidence in our plan to reduce our cash cost to $4.2 billion in 2027. These actions are very important to help us achieve our cash breakeven targets in 2028.

As we make these cost improvements, we are seeing continued use of AI across Moderna. We rolled out GPT Enterprise in 2024 and established widespread GPT literacy across the entire organization. Today, 100% of our knowledge workers are active daily users of ChatGPT.

As you can see on slide 22, GPT users have grown very fast at the company. And in 2025, we enhanced AI tools to allow for deep research capabilities allowing for the creation of comprehensive report without compromised quality of output. An example of a deep research application is the creation of target product profiles. This AI-based activity greatly reduces the amount of time it takes on product planners to create marketing strategies.

We're excited about how AI has already improved our business. And given the doubling of AI capabilities every six to seven months, we are working hard to continue to reinvent our company across each business process, department, and team. We're excited about the coming months and quarters as we have a lot of important catalysts. First, of course, the potential approvals of seasonal flu and the flu + COVID programs based on the

data Stephen shared with you. We're also eager to get the CMV Phase III efficacy data later this year. Norovirus Phase III readout is, of course, subject to gas accruals.

In Oncology, we look forward to the readout of our ongoing Intismeran Phase II five-year durability data in adjuvant melanoma. And of course, we look forward to a Phase III adjuvant melanoma trial readout for (inaudible).

As Stephen said in oncology, we are looking forward to sharing the Checkpoint Phase Ib data at ESMO in Berlin in October. And as (inaudible), we look forward to sharing the Phase II data of this program. PA is already in restriction study, and MMA will be very soon.

I'm pleased with the progress we have made on all three of our priorities over the course of the first six months of the year. We now have three products approved by the US FDA. We are highly encouraged about the progress in the pipeline and very pleased by [approval]. In our financial discipline, we have accelerated our plan for cost efficiency and expect to deliver an additional $400 million of cost savings this year.

I want to thank the team for all the great work that was done this quarter. We are very focused on executing those priorities going forward. This work allows to be focused on our mission: to deliver the greatest possible impact to people through mRNA medicine.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Salveen Richter, Goldman Sachs.

Salveen Richter - *Goldman Sachs Group Inc - Analyst*

I was wondering if you could put the changes to CMV in context for us and just help us understand the rationale behind the addition of the secondary end points. And then secondly, as we look to the individualized neoantigen therapy, and I know we're going to data at ESMO. Could you help us understand the cadence of data reads over maybe the next 12 months or so as we look to some of the other programs to mature? Thank you.

Stephen Hoge - *Moderna Inc - President*

Thank you, Salveen. So first on CMV secondary endpoints. Obviously, we're pleased to now have sufficient primary endpoint cases, which, as you know, were based on primary prevention of infection in immunogenicity implants, so antibodies against antigens not the vaccine. But there's a lot of other data that will help inform the potential value of a CMV vaccine, including looking at things like the presence of virus in bottling fluids and/or other markers or measures of infection that could be quite relevant for the use of the CMV vaccine across a wider range of populations, including even in the congenital CMV space.

Given that this is now the final analysis and as we've accrued a large number of cases and a lot of data, including against some of those secondary potential end points, we want to make sure that we reflected those in the final analysis plan as we hope that we will see a positive primary endpoint and also get the benefit of some of those secondary powered endpoints in the totality of data that would come out of the study.

I'll just remind you again that the best approach for doing this is while we are completely blinded. So the company does not know the results on the primary or any of the secondary. We are just making sure to protect the integrity of the study that we update the scale analysis plan and receive approvals for it prior to initiating that analysis with an unblinded team at which point we would then become unblinded the results after the DSMB.

And so this is just making sure we're protecting the integrity of the study. And we think it's a prudent decision to take a little bit of time here to update all those documents prior to conducting the analysis. Really look forward to that result in the fall. As it relates to the cadence of results on Intismeran, we're fully enrolled in the Phase III, as we noted, for the confirmatory study in melanoma. We are accruing events. We continue to hope that we will be able to have a successful interim analysis for efficacy on that study on the timelines we previously mentioned.

We have a number of other studies that are randomized. Actually, all of the Phase III and Phase II studies are randomized controlled studies. And several of those could read out similarly in the near term, including the studies in bladder cancer, particularly those that are largely enrolled as well as renal cell carcinoma. So those are event driven.

And so as is always the case for events studies, it's hard for us to predict exactly when we'll have sufficient data to conduct those interim analyses. But I do believe that in the coming year or two, there will be a consistent cadence of results from these randomized studies that will come out, hopefully first with a successful Phase III adjuvant melanoma study, but really soon thereafter with some of these Phase IIs and then moving into the lung cancer space.

Operator

Eliana Merle, UBS.

Eliana Merle - *UBS AG - Analyst*

Can you discuss how we should think about pricing for the COVID vaccine in the US this year and what your expectations are for net price? Or I guess, how pricing this year would compare versus last year? And any takeaways from your contracting discussions so far? Thanks.

James Mock - *Moderna Inc - Chief Financial Officer*

Sure. Thanks, Ellie. Yeah. So what I'd say is in the US, we've given a range of $1 billion to $1.5 billion. And as I mentioned in my prepared remarks, we put in variability for competitive pressures, which gets into contracting and pricing, to your point, to your question, as well as vaccination rates. First on vaccination rates, if you look at the first half, as I mentioned, when we look at the spring booster, it was down roughly 10% or 11%.So that makes us feel good. It's a smaller sample size. But as we go into the second half, it's the only barometer we have heading into the second half.

As it pertains to pricing and contracting. Contracting is basically complete now. So we will look to the second half and pricing is also completed there. We're also looking at mNEXSPIKE in there as well. I would say just right now, all those factors are within the range, and we have confidence within that range. So I don't really want to be specific on pricing or our share at this point, but it's factored into our range, and we feel confident in it.

Eliana Merle - *UBS AG - Analyst*

Understood. Thanks.

Operator

Michael Yee, Jefferies.

Michael Yee - *Jefferies LLC - Analyst*

Appreciate the opportunity for two questions. One is on CMV. I just wanted to follow up for Stephen. And maybe just talk to expectations about what you guys think is a positive readout, both on [VE], but also what is a good readout on the secondary endpoint that would help payers or patients or clinicians think about the value of CMV, given this novel type of vaccine for patients?

And then second, obviously, there has been various changes within FDA and CBER and within the ACIP, I just wanted to understand if you think that the dialogue remains very positive? And how are you expect things going forward? Thanks.

Stephen Hoge - *Moderna Inc - President*

Great. Thank you, Michael, for both. So first, on the CMV results, we powered the study, and as we've said, we believe the product will have an impact if the vaccine efficacy in the primary endpoint is better than 49.1%. That was a lower bound acceptability threshold for the primary analysis against preventive infection. That's because you might say, well, 49% or 50% is that a substantial benefit. If you think of all of the burden of disease associated with CMV over a lifetime, a 50% reduction in that would be a pretty profound benefit, we believe, on public health and for individuals.

There is complexity in terms of the individual indications because prevention of infection is one thing, but there's going to be a need to demonstrate value. Some of that will be demonstrated post approval with some of the real-world evidence generation studies. That always happen around vaccines. But we wanted to maximize the value we get of secondary endpoints in this study because we have such a rich study of information. And those include looking at things that you might think of as the persistence of virus in the blood or in the urine, the shedding and whether or not you were able to control that latent infection.

I'll remind you that in their EBV vaccine Phase I study, which we shared previously a year ago. We were able to show quite strong impacts on the rates of virus, the presence of virus upon -- over time in patients that were EBV-positive who received our EBV vaccine, different program, but shows the level of control that we were excited to see in that program. If we saw something similar here in CMV, we think that would speak to the potential benefit about the risk of congenital transmission from, let's say, a pregnant mother who's becoming infected to her unborn child as well as other potential benefits related to the chronic issues, health issues that can come from CMV.

Obviously, for those, we don't have a prespecified hypothesis in the primary endpoint but we would love to see efficacy as good or better than what we're seeing in the primary of 49%. So 49% feels good for us, that's where we designed the study, and we are looking forward to it. Obviously, we hope to do better than that. But we will ultimately look to the totality of the data to understand the value of the product and given the burden of CMV in health systems and for individuals. We're quite hopeful that we'll be able to demonstrate that value quite quickly, including out of this Phase III study with the new secondary endpoints.

As it relates to the CBER changes and some of the ACIP changes, I'll just say that we continue to work closely with our review teams across all of our products. We are very grateful for the three approvals that happened in the last quarter. I will note that they happened on time, and that was through the, obviously, the incredibly diligent work of the folks at FDA to conduct those reviews in a rigorous way, and we continue to feel that those productive dialogues are going on now even on our existing files for the seasonal update.

We will always make sure that we provide prompt and fully transparent answers to the agency and work closely with them so that they can conduct that work and we're incredibly grateful for that. As well as CDC and ACIP, where we get questions that they need information on so that they can guide public health, we'll make sure that we provide that information. And we look forward to working with both CDC, ACIP, and FDA and CBER to continue to advance our pipeline and our mission.

Michael Yee - *Jefferies LLC - Analyst*

Thank you.

Operator

Tyler Van Buren, TD Cowen.

Unidentified Participant

This is Greg on for Tyler. Do you have any early indications of what demand for COVID vaccines might look like this upcoming fall and winter season based on interactions with customers? Or will we need to wait to see early uptake at the end of this month or early next month? Thank you.

Joseph Stringer - *Needham & Company LLC - Analyst*

Yeah. Look, I think first, let's separate outside the US versus inside the US part of that question, I think that that's probably more focused on the US. But outside the US many of our government customers are purchasing through advanced purchase agreements. And so those indications are pretty firm. You can see that in our even how we're guiding forward. And so some of those are under advanced purchase agreements. Others are under tenders that have been completed and published in those countries, and that feels quite stable.

In the US, with customers, what I'd say is we saw a quite solid spring booster campaign. If you look from March 1 forward, the actual volumes in the spring booster campaign in the US were only slightly down from last year. And if you actually look at the 65-plus population, which is the core population, we think, going forward, given the new labels and framework for recommendation, it was actually down only 1% or 2% from March 1 to the end of the quarter, June 30, which I think speaks to the realization that those at high risk of severe COVID-19 continue to be compliant with public health recommendations and want to protect themselves even in the spring campaign.

That has been the same experience, therefore, of our customers in the retail channel and elsewhere where they have seen that evidence in the last four months. And as we look to the fall, we obviously have some uncertainty, both about what the ultimate ACIP recommendation will be, as well as some of the other market uncertainties that exist. But we all want to be prepared to deliver a season that could be in line with prior seasons if the trends continue from the spring till now.

So we're going to remain cautiously optimistic. Certainly, our customers are preparing to make sure they have vaccines available if their customers and patients show up and the early signs are encouraging. But we need to be careful going into the fall. We think we really won't know until the end of the third quarter, until the end of September. As is always the case, for our seasonal business, which is we'll really get a clear picture in the first six weeks of the season as we launch.

Operator

Geoffrey Meacham, Citigroup.

Unidentified Participant

This is Charlie on for Geoff. Two real quick questions. You mentioned additional cost-cutting area that you could target. You noted that R&D is a primary driver of costs right now. How might you balance the need to bring later-stage infectious products market and also the need to shift away from seasonality factors that current products have?

And then second, on CMV, these secondary end points, the decision to add them, did they come on the back of interactions or discussions from FDA? Some color on that would be really helpful. Thank you.

James Mock - *Moderna Inc - Chief Financial Officer*

Sure. Yeah. Thanks, Charlie. So I think the first question was on how are we balancing our late-stage pipeline. I mean we still think we are investing quite a bit in our late-stage pipeline. So $3.6 billion to $3.8 billion is still significant, particularly, we are very conscious of where we are from a revenue standpoint. And we've made this decision and really stood by it for the last two years. We laid this out in 2023 that we were going to invest in our late-stage pipeline.

We continue to do that. We are actively adjusting as we go, and we will continue to adjust as we go. And that's why we're taking our cash costs from $9 billion down to $4 billion. But at the end of the day, you also mentioned seasonality. We think we are building a diversified portfolio that is not just seasonal. We do want to complete the respiratory portfolio that will be stronger when we have all the products together and give us more ability to compete.

But then when you look at CMV, our oncology pipeline and our rare disease pipeline, those aren't as seasonal. And so we believe that we are balancing both the need to complete the respiratory portfolio, invest in our late-stage pipeline, and invest in diversification in the company. And we've been doing that for the last two years, and we'll continue to do it, but we have had to adjust it down. So we did have greater ambitions, but we will continue to adjust and have adjusted, and I think that's what we're seeing.

Stephane Bancel - *Moderna Inc - Chief Executive Officer, Director*

And maybe just to add to Jamey's point, we've also said that we will not invest in Phase III studies for new latent vaccine. So as you know, EBV, HSV vaccines, but we also say that we might be looking for partners, other project financing or pharma partners. And the Rare Disease, of course, small in terms of dollars. We also said we're going to focus on PA and MMA for now. We'll advance more programs later, but now we need to be financially disciplined.

And in Oncology, as you know, for Intismeran, Merck is paying 50% of the cost, which is why, as Jamey explained, we have discussed this mechanical effect that is based on the strategy we decided to pursue to make sure that we drive back the company to profitability in 2018.

Stephen Hoge - *Moderna Inc - President*

CMV question -- and on the CMV question, so just a little, again, sort of overall framing on this, we remain blinded to the primary results and the secondary results that are in the study. The interim analysis that we announced much earlier in this year was only on that primary endpoint, that's the design of those studies. But as we did not meet the criteria for early success in that interim analysis, we then proceed to the final, and the final has much more information in it.

Obviously, we leave the primary endpoint unchanged, and we'll test against that. But if that is successful, there is an opportunity to pass down the alpha to powered secondary endpoints as well as there's a final opportunity for us to say, are we getting all the information we want from the blinded analysis prior to that unbinding event? And internally, at Moderna, we identified that there is -- we've actually been very successful in collecting data in the course of the study across a range of different potential endpoints. And we wanted to elevate some of those into that secondary endpoint analysis.

In order to do that, while blinded, we have to then update the statistical analysis plan. We did consult with regulators as we are doing that. And we want to make sure that is done in the utmost to a gold standard, high-integrity way prior to conducting the analysis that we can get the full benefit of that additional information that is in the study. So again, we remain blinded. This is just a diligence matter of making sure we get this updated in the right way, and then we'll look forward to proceeding forward with that analysis.

And we have done that in consultation, obviously with regulators, but we initiated that ourselves. Last point, I just can underscore, we will still expect this in 2025. At this point, we have the data in hand. It is literally just making sure we dot our Is and cross our Ts before conducting that analysis this fall.

Operator

Courtney Breen, Bernstein.

Courtney Breen - *Sanford C Bernstein & Co LLC - Equity Analyst*

A couple of pieces that I wanted to just touch on. First, with the INT, it looks like you've added the first-line melanoma in there. How do you think about kind of patients being treated over the course of their disease. You're already kind of hitting them in the early stages of the adjuvant space and now popping up with a new first-line trial for the metastatic space. Could you imagine a world where patients might get kind of an INT twice in the course of their disease state if they were to progress? Or will this be a more narrow patient population in the first line, those that perhaps haven't had it in an earlier stage.

The second question that I did want to ask was just in terms of the kind of employee headcount cost cutting that you have just announced. Can you just add some more context, and apologies if I've missed this, on kind of where you are focused with kind of removing some of that headcount? Are there any places that you're adding to kind of enhance efficiencies? And so just talking about kind of what the ins and outs might look like to get to that new employee headcount. Thank you.

Stephen Hoge - *Moderna Inc - President*

Thank you. I'll take the INT question first. So as you mentioned, we are looking at first-line metastatic melanoma. We look forward to a day when melanoma patients broadly are getting INTs early in the adjuvant setting. But right now, the reality is as we're not yet approved and being used in that space, there's still a substantial need in frontline metastatic. Your question was sort of could we expect a world maybe in that distant future where we are being used in both places. And I think the answer is yes.

I'll remind you, it's an individualized treatment, an individualized treatment we make on a biopsy of your tumor at the time of when it happens. So it's conceivable that you could get a durable benefit in the adjuvant setting and maybe very much more distantly have a metastatic event. And the neoantigens in your tumor might have changed. So the actual INT you would get in that frontline setting would actually be updated for the evolution of your own personal cancer.

And that would be a world where you can obviously see the potential for treating early and treating late. That's speculative in the sense that it's far out there, and we'll have to prove those things. But certainly, we could see a world where people are receiving different versions of their individualized neoantigens therapy throughout the treatment of their cancer.

Stephane Bancel - *Moderna Inc - Chief Executive Officer, Director*

And I'll take the second question on employees, Courtney. If you look at it, basically, there's a few buckets, clearly the manufacturing driven by productivity, whether it's technology productivity or processes or other things we are doing. In R&D, as we talked about a lot -- and again, this is part of our strategy. We are not investing in new Phase III study in respiratory. So as those phase out, of course, there are some capacity that we need to kind of resize as you can imagine, and we're not starting new ones.

We're not starting later on Phase III. And then G&A is a lot of productivity across the board. So we'll, of course, continue to hire, I think if you check, check, I think a week ago, there's still like 150 position on Moderna's website right now. We are hiring as we need to grow the business, to prepare the launches. So of course, this is very important.

Operator

Cory Kasimov, Evercore ISI.

Unidentified Participant

This is [Adi] on for Cory. I wanted to ask a little more on the decision to start the first-line metastatic melanoma trial for Intismeran. What does this suggest about what you're learning about the product, where it might be best suited to work and your evolving confidence in the program?

Stephen Hoge - *Moderna Inc - President*

Thank you for the question. Look, we continue to follow the randomized Phase IIb results from our adjuvant melanoma study. And I think as we have seen in the repeated updates, and we hope to provide a future updates on that, as I mentioned previously, we continue to have enthusiasm from that study. And that really lays the foundation for why we are optimistic about the overall program.

If you look across where we have made with our partner, Merck, the most sizable investments, we have obviously been looking most substantially in the adjuvant settings. And that makes sense to us where the burden of the tumor is the lowest and where your immune system has the greatest chance of achieving a really significant response. And so I don't want to lose sight of the fact that we still believe adjuvant settings are important.

I'll also note that we've gone for some monotherapy smaller studies that we're starting to look at, which have us looking even earlier than adjuvant in some ways. And so we're quite enthusiastic about the program potential from adjuvant and earlier.

That said, we also want to assess diligently whether or not there's an opportunity for us to do late stage, particularly in the metastatic indication. And that's where metastatic melanoma made the most sense. It was also enabled by some progress we've really made on the manufacturing side.

Now I will just make a last comment on the metastatic indication is that those are patients that if they're unfortunately at that stage, they tend to progress quite quickly. And we need to be sure that we can deliver highly efficiently, highly reliably a product for them inside of six weeks or hopefully even better from a quick turnaround perspective so that they can start being treated by the drug post enrollment in the study.

And so it's quite pragmatic to say, let's build up the capability in the adjuvant and early space, but then now go in a targeted way and look in later stage. And what we've really seen in the Intismeran clinical portfolio, over now, many studies and over 1,000 patients treated is this opportunity for us to look in the late stage with a rapid turnaround and highly efficient manufacturing system.

But I don't want to lose sight of the fact that we still really believe in the adjuvant space, that is the major place that we're betting, but we do believe that earlier than adjuvant and perhaps in the front line are worth looking at as well, and we'll be doing that in the studies that we just announced.

Unidentified Participant

Got it. And then just a follow-up, can you discuss any regulatory interactions you have had on the path ahead for Checkpoint AIM-T? I see on Slide 12, that is now expected to be filed for approval by 2028? Thank you.

Stephen Hoge - *Moderna Inc - President*

Thank you for that question. So 4359, we have been engaging with regulators. Those are early stage. I won't get into the specifics of them. I'll remind you, we're just now moving into Phase II. And so these are really Phase I stage conversations, which would make it premature to go too much into specifics. That said, we are investing behind the program.

And as we announced at the last quarter, we're investing as though this could become one of our submissions over the next three years, as you identified sort of by 2028, that really is a statement about our prioritization of the program and our conviction given the very early stage data and not necessarily a statement about anything we've done either out of Phase II and subsequent discussions with regulators about approval time line. So it's our prioritization of the program that brings that forward. But we believe it is possible.

Operator

Luca Issi, RBC.

Luca Issi - *RBC Capital Markets Inc - Analyst*

Maybe one, Stephane, bigger picture, can you maybe just talk about business development here? We've obviously seen a lot of assets being in-license from China, including obviously, one of your competitors that actually licensed the assets and even flipped it to pharma for some means of profits. Given your long-term ambition to become a key player in oncology, are you actively spending time in China, and if so, are you just looking at strengthening your mRNA capabilities? Or are you open to other modalities?

And then maybe second, Stephen, can you just talk about the COVID plus flu how should we think about the sequence of the filing here with the FDA? Is it fair for us to think that you first need to get approved for flu monotherapy and then you can file the combo, or can you possibly do both concurrently? I guess any color there, much appreciated so we can think about timelines. Thanks so much.

Stephane Bancel - *Moderna Inc - Chief Executive Officer, Director*

So on the first question, as we've said before, we have such a productive platform in mRNA that we have an abundance of assets. Actually, what we are doing, as you heard on the cost structure, we are deciding not to take forward to Phase III asset that we believe deeply into, take EBV, for example, because we ought to be financially disciplined. But we've said we believe this vaccine is really important for patients. As you know, we have two program in EBV. There is a prophylactic program to prevent mononucleosis and potentially long-term sequelae of MS and there's a potential therapeutic program for people that are already sick.

And we believe those programs have to move forward, which is why, as we've said on previous calls, we are actively talking to potential pharmaceutical partner and potential product financing partners for several of those assets that we cannot prosecute forward alone because they are great assets, but we need to be financially disciplined at the same time.

We've always thought that partnering is a great way to access assets that are non-mRNA technology. I mean, a good example, of course, is our important strategic partnership with Merck with KEYTRUDA. We could have decided to develop our own PD-1, everybody don't think this was the right thing to do.

But partnering with Merck in term of having an approved product and the right capabilities was. So we're always going to look at the biology. That's what has always driven us to try to find the best way to help patients and to create the best asset. And if we need a partnership, we will do so.

Stephen Hoge - *Moderna Inc - President*

And thanks for the question on the COVID-flu combo. So look, I'll first say, concurrent is certainly possible. You're asking whether it's theoretically possible. I think we think it is. But as a practical matter, there will probably be some sequencing. And as a practical matter in the case of the US FDA, it's likely that the flu vaccine will be sequenced first for all of the reasons that are obvious. It's that a chance to review that efficacy data from that flu vaccine feels very important for ungating the flu-COVID combination.

Now the one caveat I'd put on that is there are markets where we continue to proceed with our flu-COVID vaccine application, including in Europe, where we have -- we believe we're going to be able to amend that file to include the flu efficacy data.

And so the answer is ultimately dependent on the different regulators in different markets. It is possible that we could proceed in parallel but for pragmatic reasons, we may proceed in sequence. And so that doesn't mean that we're delaying for 1 to be approved before we submit, but we are allowing substantially through to proceed before proceeding with the flu-COVID, again, market to market, different answers.

Luca Issi - *RBC Capital Markets Inc - Analyst*

Thank you so much.

Operator

Gena Wang, Barclays.

Gena Wang - *Barclays Services Corp - Analyst*

I have two, maybe just follow flu-COVID comments here or discussion here. So any latest thoughts regarding flu combo submission requirement? This is specifically regarding the FDA. And then second, regarding the CMV, how do you decide the statistical hierarchy for the secondary endpoint? And also given the study basically already completed, is it fair to say in two months, we will see the data?

Stephen Hoge - *Moderna Inc - President*

That's very specific questions. Thank you, Gena, for all of them. So on the flu-COVID, we're actually beginning those consultations with the FDA. And so we'll wait for a week for us to have guidance from them on what their requirements are. But the previous review, it was clear that we needed to submit the flu efficacy results and confirm the correlative protection from that study that we now have.

And so we will go back and confirm that that is necessary, as well as understand any other information the FDA would want to see in the application. When we've had that consultation, we'll be able to provide more clarity. I don't have that now.

As far as CMV in terms of the hierarchy. We have not yet disclosed what the powered secondary endpoint will be or some of the other things that we are looking at. We will, once we are obviously unblinding the study, but the -- what we're looking to do is a hierarchical testing, as you can imagine, that we're passing the alpha down to that secondary. And then we're also making sure that we characterize all the additional secondary endpoints that we think will be useful in terms of characterizing the performance of the vaccine on a number of different immunologic and virologic measures.

Last question, when will we see the data? We have completed the study. We are going to be diligent and careful in dotting our Is and crossing the Ts. We have not completed the analysis. And so will we have most of the data? I would say that we are completely blinded to those results.

And so it will take some time to first make sure that we have all the appropriate approvals on the update to the statistical analysis plan, everywhere we want. And then we will initiate the analysis, and there will be some period of time for an unblinded statistical team to conduct all the correct analysis and review that DSMB and then will be informed. We do expect that to happen this fall. I will not say whether or not we expect it to happen within the next two months because honestly, I don't exactly know today how much time it takes to go through those approvals and complete those analysis, but we're quite confident that it will happen probably.

Gena Wang - *Barclays Services Corp - Analyst*

Thank you.

Operator

Ladies and gentlemen, that concludes the Q&A portion of today's conference. I'd like to turn the call back over to Stephane for any closing remarks.

Stephane Bancel - *Moderna Inc - Chief Executive Officer, Director*

Well, thank you, everybody, for joining us today. We really appreciate it. We look forward to speaking to you in the next days or weeks. Have a nice day and a good weekend. Thanks.

Operator

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