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OVERVIEW:

Company Summary

REFINITIV

CORPORATE PARTICIPANTS

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

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

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

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

Stephen Hoge *Moderna, Inc. - President*

CONFERENCE CALL PARTICIPANTS

Alec Warren Stranahan *BofA Securities, Research Division - Associate*

Boran Wang *Guggenheim Securities, LLC, Research Division - Associate*

Edward Andrew Tenthoff *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

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

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

Manos Mastorakis *Deutsche Bank AG, Research Division - Research Analyst*

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

Simon P. Baker *Redburn (Europe) Limited, Research Division - Head of Pharmaceutical Research*

Tyler Martin Van Buren *TD Cowen, Research Division - MD & Senior Equity Research Analyst*

PRESENTATION

Operator

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

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

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

Thank you, Kevin. Good morning, everyone, and thank you for joining us on today's call to discuss Moderna's Second Quarter 2023 financial results and business updates. You can access the press release issued this morning as well as the slides that we'll be reviewing by going to the Investors section of our website.

On today's call are Stéphane Bancel, our Chief Executive Officer; Stephen Hoge, our President; Arpa Garay, our Chief Commercial Officer; 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 will turn the call over to Stéphane.

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

Thank you, Lavina. Good morning, or good afternoon. Today, I will start with a business review of our second quarter. Stephen will then review our clinical programs before Arpa gives an update on our commercial progress and plans. Jamey will present our financial results, and I will come back to share some final thoughts.

In Q2, we reported revenues of approximately $300 million, reflecting the seasonal nature of endemic respiratory vaccines. Given our investments in our 4 infectious disease vaccine programs, which are in Phase III and our oncology program also in Phase III, this off-season quarter sales resulted in a GAAP net loss of $1.4 billion, GAAP diluted loss per share of $3.62. We ended the quarter with a cash and investment balance of $14.6 billion.

We continue to execute on our capital allocation strategy, prioritizing organic growth of our platform with investments in our business. In Q2, we invested $1.1 billion in R&D, continuing investments in late-stage clinical programs and progressing our pipeline. SG&A costs were approximately $300 million. Capital investments were approximately $200 million.

Year-to-date, our external investments were all strategic collaborations with the exception of OriCiro in Japan, which was an acquisition. OriCiro was renamed Moderna Enzymatics and is being integrated into Moderna manufacturing process development organization.

From a capital return perspective, we repurchased 4.4 million shares in Q2 for a total of $628 million.

Now turning to commercial and late-stage clinical updates in the quarter. With the submission of our XBB updated COVID-19 vaccine applications to regulators globally, we are now awaiting approval to start fall of 2023 sales. As you will hear from Arpa shortly, we're updating for COVID-19 sales expectation for 2023 to a range between $6 billion and $8 billion. This range reflects additional contracts in the U.S. commercial market and other countries. This range is wide given the uncertainty on the U.S. vaccination rate.

Our commercial team is also preparing for the 2024 launch of RSV, our next respiratory commercial product. Regulatory applications have been submitted in major markets around the world. We've also started to manufacture mRNA-1345 in preparation for the launch. As a reminder, at launch, this product will be in a pre-filled syringe presentation, which combined with a strong efficacy profile, we position very well on product to health care professionals.

In oncology, for mRNA-4157, or Individualized Neoantigen Therapy or INT, we are continuing to scale up manufacturing to support clinical development and commercial markets. We are very pleased to report our Phase III study in adjuvant melanoma has begun enrolling patients in July.

We will plan, on Slide 6, our updated company profile. The breadth of our late-stage pipeline means we could see multiple launches in '24, '25 and '26.

Turning now to Slide 7. I am proud to share that Moderna has been named as one of the world's most innovative companies in 2023 for pioneering AI-driven innovation by the Boston Consulting Group. As many of you know, AI has been part of the foundation of Moderna's research and development programs for several years. We have built our own AI models for protein and mRNA engineering, data analysis, regulatory interactions and many more other use cases.

As we continue to be an AI leader in biopharma, one of our key modular mindset is that we digitize everything possible as we recognize that this will be central to the impact we have with AI. As of 2023, AI training is required for all Moderna's team members and will facilitate this training at the corporate level through our AI Academy. We have challenged everyone across all of our business functions at Moderna to incorporate AI into their everyday's workflow.

I'm happy to share our AI implementation is accelerating throughout Moderna. Our secure large language model is called mChat. As you can see on the graph, our mChat usage has grown rapidly amongst our employees since its introduction on May 18. Around 50% of our employees use it already only 60 days after launch.

With that, I will now toss to Stephen for an update on development programs.

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Stéphane. Good morning or good afternoon, everyone. Today, I'll review the progress of our key clinical programs in Moderna, and I'll start with our respiratory vaccines.

On the left-hand side of the slide, we have our commercial and late-stage clinical pipeline program against 3 important respiratory viruses, COVID-19, flu and RSV. I'll share some updates on these programs in a moment. Our next-generation programs have made substantial progress over the first half of this year, including mRNA-1283, which is enrolling participants in a Phase III study and our next-generation influenza vaccines, which are both in Phase II. We currently have 6 combination vaccine programs addressing adult and pediatric populations. Our combination vaccines are designed to address the largest health care burdens caused by respiratory infections while providing multiple advantages such as increasing compliance and reducing administration costs.

Turning to our COVID program. We have submitted our applications for approval and authorization of mRNA-1273.815, our updated monovalent COVID-19 vaccine targeting the XBB.1.5 variant. Recall that the June VRBPAC meeting, the committee recommended an XBB-targeted monovalent vaccine with a preference for the XBB.1.5 strain. This recommendation was adopted by the FDA and is in concordance with the EMA and WHO guidance. In the U.S., the CDC ACIP is expected to publish recommendations and guidelines for the use of updated COVID-19 vaccines following approval and authorization this fall.

On Slide 11 are the clinical data our team presented during the June VRBPAC meeting. Data from a subset of our Phase II/III study with mRNA-1273.815 demonstrated potent neutralization against XBB.1.5 and other variants of the XBB lineage. We're proud that Moderna was the only company that presented clinical data with an XBB.1.5 candidate in advance of the season, which we believe may help uptake of this important vaccine.

Moving to RSV. As Stéphane mentioned earlier, we are pleased to be on track for regulatory approvals in 2024. Earlier this month, we announced a rolling submission to the FDA, and we plan to use a priority voucher to accelerate that review. We also filed additional regulatory applications in Europe, Switzerland, Australia and the U.K. We're incredibly encouraged by the profile of mRNA-1345 and look forward to the expected commercial launch next year.

Next, on the seasonal influenza program. I'm pleased to announce that our P303 study is fully enrolled, and we look forward to sharing an update this quarter. P303 is testing an update to mRNA-1010 that is designed to increase the HAI neutralizing titers against the B antigens. This is a safety and immunogenicity Phase III study that we believe will support accelerated approval of the updated mRNA-1010 candidate.

Now turning to our latent vaccines on Slide 14. Our Phase III CMV vaccine study in women of child-bearing age is ongoing and I'm pleased to share that the trial has enrolled more than 80% of participants. We look forward to full enrollment of that study soon.

In our early clinical programs, EBV, HIV and VZV vaccine trials are ongoing and our HSV program is in pre-clinical.

Now let's look at our mRNA therapeutics portfolio on the next slide, and I'll highlight a few programs. We are excited to announce that our Phase III melanoma study with INT is now enrolling. And I'll share the Phase III design in a moment. Our rare disease programs addressing major unmet medical needs in propionic acidemia, methylmalonic acidemia and GSD1a are ongoing, and we will look forward to sharing updates when the data are mature.

Indeed, during the quarter, we presented an update on some of our PA program data at ASGCT. The dose confirmation part of the propionic acidemia study is currently ongoing. And lastly, our collaborators at Vertex are continuing to enroll in dose cystic fibrosis patients in the single ascending dose portion of that Phase I study.

Now on my last slide today, I want to take a moment to share the exciting Phase III trial design for our Individualized Neoantigen Therapy, or INT. This Phase III study is a randomized double-blind placebo-controlled study of the combination of INT plus KEYTRUDA against placebo plus KEYTRUDA

in patients with resected melanoma at high risk of recurrence. The study will enroll approximately 1,089 resected melanoma patients, Stage IIB through IV with a 1:1 randomization. Each patient will receive up to 9 doses of INT every 3 weeks and KEYTRUDA every 6 weeks in the active arm or 9 doses of placebo every 3 weeks and KEYTRUDA every 6 weeks in the comparator arm. The primary endpoint is recurrence-free survival and secondary endpoints include Distant Metastasis-Free Survival and Overall Survival.

I'm incredibly impressed with the collaboration between the Moderna and Merck scientific and clinical teams to rapidly stand up and begin enrolling this Phase III study.

And with that, I'll turn it over to Arpa.

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

Thank you, Stephen, and good day to everyone. I'll start with a review of sales in the quarter and the first half of 2023.

In the second quarter of 2023, we reported approximately $300 million of COVID vaccine sales, which was in line with our expectations given the seasonal nature of endemic respiratory vaccine businesses. Sales of $2.1 billion for the first half of 2023 met our expectations. As a reminder, the sales in the first half were predominantly from mRNA-1273.222, which is our COVID vaccine targeting the BA.4, BA.5 variant. As you heard earlier from Stephen, regulators and health authorities around the world have selected the XBB.1.5 variant for the fall 2023 season. We have submitted applications to regulators globally for our updated vaccine and we are now awaiting approvals and authorizations. Subject to regulatory approvals, we expect additional sales in the second half of 2023, primarily from mRNA-1273.815.

Turning now to the 2023 COVID sales outlook. We are updating our COVID sales expectation for 2023 to be in the range of $6 billion to $8 billion with the key variable being vaccination rates from the United States. Our 2023 sales mix consists of $2.1 billion in sales already recorded in the first half of this year, another $2 billion in sales from previously signed advanced purchase agreements for the second half delivery from several countries, including those listed in the middle column on this slide.

Recent discussions with customers around the world have resulted in confirmed contracts of $2 billion for delivery in the second half of this year, updated from the originally expected $3 billion. Approximately $1 billion of the original $3 billion are now expected to be deferred to 2024. Also now included in the total expected 2023 COVID sales range of $6 billion to $8 billion is an additional $2 billion to $4 billion in sales expected from signed and anticipated commercial contracts in the U.S. as well as other markets such as Japan and the EU. The U.S. commercial contracts are a sizable portion of additional new sales expected in the second half of this year, so let me provide some color on that market in particular.

As you are aware, the COVID vaccine market in the U.S. has shifted to a commercial market with the transition from the pandemic to the endemic phase. In the U.S., the commercial vaccines market is made up of many different customer segments, including retail pharmacies, wholesalers, group purchasing organizations, integrated delivery networks, health systems, government entities, employers and other providers. Today, I am happy to report that we have signed contracts in each of these customer segments and continue to work on additional contracts. We are ready with ample supply to be shipped upon regulatory approval.

Our science contracts give us visibility into the expected U.S. launch in the coming weeks and confidence in the additional sales we expect in the second half of 2023 from new orders.

Let me now turn to Slide 21 to help frame the fall of 2023 U.S. COVID market. As I mentioned earlier, a key determinant for the market size in the U.S. will be vaccine uptake or shots and arms during the upcoming September to December time frame. As I've mentioned before, our expected 2023 sales range of $6 billion to $8 billion will be primarily driven by vaccination rates in the U.S. market. Earlier in the year, we provided parameters that informed our U.S. fall volume forecast for 2023, which included the roughly 50 million doses administered in the U.S. in the fall of 2022, 82 million Americans in the high-risk category for those who are over 50 with a comorbidity or those over the age of 65 and an average of 150 million doses of flu vaccines given in the U.S. every year for the last 9 years, which we believe is a reasonable proxy for a seasonal respiratory vaccine especially given the higher burden of disease with COVID.

These parameters supported a volume forecast of 100 million doses for the U.S. market for fall 2023, but the fact of the matter is, in this first transition year to a commercial endemic market, it is difficult to accurately predict market volumes and predict how many Americans will come in this fall for their shots. As such, we look to Southern Hemisphere countries where the COVID season occurs during their fall/winter months to inform potential vaccination uptake in the U.S. as well. Specifically in Australia, where they are just completing their 2023 COVID season, the vaccination rate was 19% and populations where the booster vaccine was recommended. The Australian data, combined with prior year comparisons indicate U.S. market volumes for fall of 2023 to be in the range of 50 million to 100 million doses and this supports our U.S. sales expectations for the second half of the year.

Moving to Slide 22. I'm excited to share the fall vaccination campaigns for the updated COVID vaccine launch. Moderna's fall vaccine campaigns are two-pronged and are focused on: first, increasing the market size through disease awareness programs and secondly, on solidifying Moderna's market share with branded promotion. With our disease awareness campaigns, we are aiming to educate on disease burden, clarify the latest recommendations from ACIP and connect COVID-19 with seasonal flu vaccines with the goal to drive consumers to get vaccinated this fall. Branded promotion campaigns will focus on driving brand preference from Moderna's vaccine running direct-to-consumer campaigns across major media channels and conducting promotions with health care providers. The commercial team is highly energized for the launch of the updated COVID vaccine.

Moving on to Slide 23. We are continuing to prepare for a potential 2024 launch of our RSV vaccine and are excited about the opportunity in front of us. We believe our vaccine has the best-in-class profile. This includes consistent high efficacy across vulnerable and older populations, as shown in the strong clinical data that we have shared. Additionally, our safety profile is well established. We now have administered more than 1 billion COVID vaccine doses using the same mRNA technology as our RSV vaccine.

In our Phase III study, most solicited adverse events were mild to moderate. An mRNA-1345 in our Phase III RSV trial has not had any reported cases of GBS events as of the April 30 cutoff date. And finally, one important differentiator for us and for our customers at launch will be the presentation of the product, which will be exclusively in ready-to-use pre-filled syringes. This packaging allows health care professionals to conveniently dose consumers with a ready-to-use formulation. We believe this will save time and reduce errors in comparison to the reconstituted drug products on the market.

We continue to invest in pre-launch activities and are prepared for next year's potential launch. Our commercial team is active globally, and our manufacturing organization is well prepared to deliver the vaccine.

With that, I will turn it over to Jamey.

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

Thanks, Arpa, and hello, everyone. This morning, I will cover our second quarter financial performance and provide a framework for our full year financial outlook. Starting on Slide 25.

Total product sales were $293 million, down 94% year-over-year, mainly driven by lower sales volume. We continue to expect 2023 to be a transitional year as we move from a pandemic to an endemic commercial market with significant seasonality. In line with our expectations, sales in the second quarter were relatively low, while we came in at the high end of our communicated range. Cost of sales for the second quarter of 2023 was $731 million.

In addition to unit-driven manufacturing costs, this includes the following charges: $464 million for inventory write-downs related to excess and obsolete COVID-19 product, unutilized manufacturing capacity of $135 million and losses on firm purchase commitments of $75 million. These charges, other than royalties, were primarily driven by a shift in product demand to our latest monovalent XBB.1.5 COVID vaccine candidate and an overall lower market size compared to our expectations at the beginning of the year.

In order to have ample supply at the beginning of the 2023 fall season, we prepared for various outcomes of the strain selection resulting in additional cost to the P&L. The fact that a monovalent was chosen also meant that we were not able to use previously manufactured semi-finished goods.

R&D expenses were $1.1 billion, which increased by 62% versus prior year. The increase in R&D continued to be driven by clinical trial-related expenses, particularly with our Phase III studies for RSV, seasonal flu and CMB. The increase in R&D is also attributable to increases in personnel costs due to increased head count to support our research and late-stage development efforts.

SG&A expenses were $332 million, reflecting an increase of 57% year-over-year. The growth in spending was primarily driven by continued investments in personnel and outside services in support of our digital initiatives, marketed products, related commercialization activities as well as our company expansion.

Income tax was a benefit of $369 million for the second quarter, mainly due to a loss from operations. Net loss for the period was $1.4 billion compared to net income of $2.2 billion last year and diluted loss per share was $3.62 compared to diluted earnings per share of $5.24 in 2022.

We ended Q2 with cash and investments of $14.6 billion compared to $16.4 billion at the end of the first quarter. The decrease was driven by our net loss in the period and an approximately $600 million of share buybacks. Cash deposits for future product supply declined during the quarter by approximately $100 million to $1.7 billion by the end of the second quarter, which was in line with our expectations.

Now turning to Slide 27. I want to give an update on the progress we have made on our capital allocation priorities. Our top investment priority has been and will continue to be reinvesting in the base business. R&D spending in the first half of 2023 increased 80% year-over-year to $2.3 billion, and we remain on track to invest $4.5 billion in R&D for the full year. We are also investing in our digital capabilities, the commercial build-out of the organization as well as expanding our manufacturing footprint. We've accelerated our capital expenditures in 2023 as we expand both our international and U.S. manufacturing footprint.

Our second investment priority is to seek attractive external investments and collaboration opportunities that will enable and complement our platform. We remain disciplined in our approach and are in multiple active discussions.

After evaluating internal and external investment opportunities, we then assess additional uses of cash. In the first half of 2023, we repurchased 8 million shares for approximately $1.2 billion and we had $1.7 billion of share repurchase authorization remaining as of June 30, 2023.

Now let's turn to our updated 2023 financial framework on Slide 28. We would like to share our thinking beyond the advanced purchase agreements. As Arpa mentioned earlier, we now expect product sales for 2023 in the range of $6 billion to $8 billion comprising of approximately $4 billion from existing APAs and approximately $2 billion to $4 billion from additional sales to the U.S., Japan, EU and other countries. As a result of recent discussions with customers around the world, we now expect approximately $1 billion of the original total $5 billion in APAs to be deferred to 2024.

Second half sales timing 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 sales split of 30% in Q3 and 70% in Q4.

We now expect cost of sales for the full year in the range of $3.5 billion to $4 billion. At this point of the year, our production costs are largely fixed and only a smaller portion is driven by the sales outcome. Therefore, we thought it would be more helpful to provide you an absolute dollar range for your modeling purposes.

For R&D and SG&A, we continue to expect full year expenses to be approximately $6 billion, with approximately $4.5 billion in research and development. We now anticipate a full year tax benefit in the range of $0.7 billion to $1 billion, driven by an assumed operating loss, R&D credits, international provisions and nonrecurring items. And finally, we continue to expect capital expenditures of approximately $1 billion.

That concludes my prepared remarks, and I'll turn the call back over to Stéphane.

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

Thank you, Jamey, Arpa and Stephen.

Moderna has a promising commercial outlook, starting with COVID. While there is uncertainty in vaccination rates as we transition from a pandemic to endemic market, our APAs and U.S. commercial contracts underpin our expected 2023 COVID revenue in the range of $6 billion to $8 billion. We believe this first endemic here will provide visibility to recurring revenue stream. I believe we will be selling COVID vaccines for a very long time and we are working to combine COVID and flu into a single vaccine.

Moving to RSV. RSV vaccine has a strong product profile and a differentiated pre-filled syringe presentation that should work through our advantage in the anticipated 2024 launch. In oncology, we are scaling our IoT manufacturing capacity to be ready for commercialization. The Phase II data are very strong, and we are now in Phase III with melanoma indication.

With our partner, Merck, we are working to prioritize indications beyond those already announced, which are melanoma and non-small cell lung cancer.

Stepping back and looking at the broad portfolio, I'm very excited that we are playing with a high-case scenario of Moderna with positive clinical data in infectious disease vaccine, in oncology, and in rare genetic disease of liver. Over the next 3 years, from '24, '25, '26, we anticipate multiple product launches across our vaccine and therapeutics portfolio that will position the company for strong sales growth. This is an incredibly exciting time at Moderna as we enter a new era with diversified revenue stream and a robust pipeline.

The platform is working, and the result will be an unprecedented number of mRNA launches in a very short time.

We look forward to updating you further at our upcoming R&D Day on September 13. That event will be live in New York City and, of course, also available online. On December 7, we'll be hosting our second annual ESG Day. This event will be online. The mission of our company is to deliver the greatest possible impact to people through MRNA medicines. This mission is especially relevant now as we approach the launch of multiple new medicines that should extend human lives and alleviate patient suffering. All of our stakeholders are poised to benefit as Moderna continues to deliver on its potential. It is a privilege for all of us to be part of this company.

We'll now take questions. Operator?

QUESTIONS AND ANSWERS

Operator

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

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

With regard to the expected additional sales for second half deliveries, can you speak to the spectrum of factors in addition to the U.S. vaccination rates that might impact reaching the higher end of that range? And can you discuss confidence that additional contracts wouldn't be pushed to 2024 as the fall season plays out?

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

Thank you for the question. So in terms of the additional sales of $2 billion to $4 billion, as you mentioned, the key factor of landing within that $6 billion to $8 billion is really around how many Americans this fall come in to get their shot. So vaccination rate is the biggest swing factor within that range. We are confident in our market share and the progress that we've been making with commercial contracts thus far in the U.S.

Additionally, outside of the U.S., to your question on additional contracts potentially being deferred, we have met with all of the different countries where we have advanced purchase agreements and have already confirmed deliveries for the second half of this year, other than the $1 billion, which was pushed into 2024. So we're confident in staying at that $2 billion range.

Operator

Our next question comes from Tyler Van Buren with TD Cowen.

Tyler Martin Van Buren - *TD Cowen, Research Division - MD & Senior Equity Research Analyst*

So with the COVID-19 vaccine sales of $6 billion to $8 billion expected for the year, how should we think about what that implies for real demand as we think about the eventual COVID-19 vaccine franchise tail? Is it $2 billion to $4 billion since the $4 billion was already locked in from APAs at the start of the year from prior years? If not, what proportion of the $4 billion of APAs would you consider true annual booster demand? Perhaps, is it the $2 billion expected in the second half? Thoughts there would be helpful.

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

Thank you for the question. So in terms of how we're thinking about 2024, I would look at the first half of 2023, where we have recently reported $2.1 billion of sales. A portion of that volume is volume that we do not anticipate as a recurring sale in the outer years, given most countries are going towards fall vaccination campaigns with annual shot. For the remainder of the $4 billion to $6 billion, we do believe that vaccine demand will remain. And over time, eventually increase as we think about the flu volumes that we believe the COVID vaccination rates will start trending to.

So as I mentioned earlier, for example, in the United States, there are about 150 million flu vaccines given every fall. What we've modeled for 2023 is the range of 50 million to 100 million. And we think over time, given the high disease burden and also as we think about future combinations, we will start trending closer to about 150 million.

Operator

Our next question comes from Gena Wang with Barclays.

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

Two very quick questions. Regarding the COVID U.S. commercial contract that signed, were there any definitive initial stocking order? And second, regarding the RSV vaccine, given that Pfizer and the GSK label language and a slow initial launch, any learning you could have for your approval and the launch prep?

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

Thank you. So I'll take the first question around U.S. contracts first. In our contracting progress, we do have minimum volume commitments across many of our commercial contracts. But most of our contracts were looking at minimum commitments and depending on vaccination uptake that we will be monitoring closely with our customers, that volume could go up over time.

In terms of the recent RSV ACIP meeting, we think the ACIP recommendation for a shared clinical decision-making will mean a more gradual uptake for the first two vaccines that have been approved. Though as we believe there is more data from both our clinical program as well as GSK and Pfizer's clinical programs, we do believe there is opportunity to potentially update that recommendation, which would, over time, lead to a broader uptake of the RSV vaccine.

Operator

Our next question comes from Michael Yee with Jefferies.

Unidentified Analyst

This is Dina on for Mike. Just a quick question on the flu update. So I saw that you guys are doing a Q3 update for the second immunogenicity study and then going on to have data in Q3 with that, but how about the efficacy study from that second infection or that -- yes, that previous infection study, what are your time lines for that? Have that shifted? Are you going to share that? And also on PCV, are you going to be sharing any additional updates on the regulatory path moving forward? Or are you sharing any other updates on lung, et cetera?

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Dina, for the question or questions. So -- so first, on the 1010 flu program, as you referenced, we have 2 ongoing. We have actually 3 ongoing Phase III studies, but 2 that are continuing to accrue data. We'll be providing updates on the efficacy study, the P302 study you referenced. And as you know, in our Vaccines Day, we talked about end of season update. And we'll also be sharing where we are in the pivotal P303 immunogenicity study. And as I said, we'll be doing that this quarter, and we're excited to continue to update on the progress in influenza.

As it relates to INT. Now INT, not PCV, that program, we had a great opportunity to provide an update to you all and everyone at ASCO just a month ago. And we're going to be, of course, at our R&D Day, reprising that and also talking to some of the other progress happening in the INT program. We are obviously working hard to get up and running in our non-small cell lung cancer, but we're really -- pivotal studies, but we're really excited by the start of the first Phase III with melanoma study now, and we'll be providing further updates in a month in New York.

Operator

(Operator Instructions) Our next question comes from Ellie Merle with UBS.

Unidentified Analyst

This is Sarah on for Ellie. Just a follow-up on Tyler's earlier question. Thinking about COVID volumes going forward, can you give more color on how you're thinking about first half versus second half, particularly any color on your expectation for first half of next year? And then on CMV, any expectation on when you'll complete enrollment? And how we should think about when we could get data and maybe anything you're seeing on a blinded basis on the event rate?

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

So I'm happy to take the first question and then we'll hand it over to Stephen on CMV.

In terms of how we're thinking about the first half versus second half going forward, in the first half of the year, sales that we expect will come from the Southern Hemisphere where it is their fall and winter season. Additionally, in some countries in the higher-risk populations, there continue to be spring campaigns and boosters, particularly for immuno-compromise, elderly and highest risk patients. So we do anticipate some sales coming in for the high-risk spring boost for the Southern Hemisphere as well as any carryover from late winter of this year into January. The majority of our sales will continue to be expected in the second half of the year though as the majority of our sales will be anticipated from the Northern Hemisphere and the fall vaccine campaign.

Stephen Hoge - *Moderna, Inc. - President*

Great. And a question on CMV enrollment. Yes, we're really excited by the recent acceleration towards completion of enrollment there. We're past 80%. We do hope to complete enrollment shortly. We've made good progress in the first half of this year. And so we haven't specifically set a target on that, but we would hope to enroll it for sure this year.

The -- then we will be accruing cases. And I think that's where it gets very interesting in tracking the CMV Phase III program. We've already started to accrue cases that we talked about in the Vaccines Day. And as we get to full enrollment, we will have more participants who can contribute cases to our first interim analysis of efficacy, which will be an event-driven analysis and so not something we can predict...

Operator

Our next question comes from Luca Issi with RBC Capital.

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

Maybe one, Jamey, if I can circle back on margins. I think your prior guidance implied 60% to 65% gross margin versus your new guidance today implies 47% gross margin at the midpoint. Can you just maybe expand a little bit more on what's driving that change today? And then maybe Stephen on flu, I think Sanofi argued that the lower immunogenicity for the B strain could actually be a class effect. So it'd be difficult for any of the mRNA player to actually have strong immunogenicity for the B strain. Wondering what are your thoughts there?

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

Yes. Thanks, Luca. I'll take the first question.

So on margins, yes, you're right. We were planning for 60% to 65%. I'd say it's largely volume driven, $1 billion of APAs pushing out to 2024 as an example. We still have the cause for those fixed into our $3.5 billion to $4 billion in addition to other markets as well. So I think our volume expectation prior to this quarter was a little higher, some due to push out, some just due to overall volume that we anticipate coming through here.

Stephen Hoge - *Moderna, Inc. - President*

And I'm aware of the argument that Sanofi made about a class effect. I'm not sure I see it the same way. I think we'll look to the data to answer that question rather than conjecture. We'll look forward to sharing where we are in the P303 Phase III study in the next quarter. And I'll leave it at that.

Operator

Our next question comes from Edward Tenthoff with Piper Sandler.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Great. Can you hear me okay?

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

Loud and clear.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Great. So thanks for all the detail in the update. And my question is kind of a little bit of a longer-term strategic one. As COVID continues to evolve and then as you ultimately seek approval of 1010 and even RSV. What is the plan for combining these from a regulatory standpoint and then also a commercial standpoint? So how do we get from where we are today with 1 approved, maybe 2 -- 3 approved vaccines next year to 1 combo approved or multiple combo approved vaccines?

Stephen Hoge - *Moderna, Inc. - President*

Thanks for the questions, Ed. So as you know, we've had -- as I said, we have 6 combo vaccines. We've got lots of clinical data out there. And we continue to look at new combinations. And if we're in a situation that we expect to be in, where we have a flu, RSV and COVID approved as well as second-generation COVID moving forward, you can be -- you can rest assure we'll be looking at multiple different combinations of those, trying to bring forward options that provide the greatest public health flexibility. Those studies, once we have the products approved, the monovalent vaccines, those studies are really just immune bridging studies, demonstrating that we can do the combination and achieve non-inferior immunogenicity and safety in those studies. They can be quite quick and they also don't need to be run in the season, as you know.

And so our goal is going to be, as we've said throughout this year, is to complete the work to move towards approval, filing and eventually, hopefully, approval of the 3 monovalent vaccines and quickly progressing into the pivotal Phase IIIs for at least 1 and multiple combos. Our goal, again, is to be launching those in '25 and beyond. So the obvious reason that they will improve compliance, deliver more value and actually decrease the administration cost of health care.

So the path is actually pretty clear from here, particularly given the strength of the RSV data and where we are in COVID, and we hope to be providing an update very shortly on flu that also provides a clear path for '24 in the monovalent launches we've guided. And then I think we'll clarify very quickly that we're starting the Phase IIIs to allow the combo launches very shortly thereafter.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

That's really helpful, Stephen. And just to clarify 1 point, if I may. When you said the pivotal Phase IIIs, those would be immuno-bridging studies?

Stephen Hoge - *Moderna, Inc. - President*

Immunogenicity -- correct. They're immunogenicity and safety studies. So very quick studies, just demonstrating. We do not believe nor is the norm from a regulatory perspective that you have to do subsequent efficacy studies once you've established the efficacy of the monovalent vaccines.

Operator

Our next question comes from Manos Mastorakis with Deutsche Bank.

Manos Mastorakis - *Deutsche Bank AG, Research Division - Research Analyst*

Basically, I just wanted to ask in terms of the COGS guidance, does that apply regardless of the revenue range? And if not, what is the sensitivity range that you could provide?

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

Yes. Thanks for the question, Manos. Yes, it does apply regardless, as I mentioned in my prepared remarks, most of this cost is fixed at this point. We've already ordered the raw materials. We've already started manufacturing. Most of our -- we have got a lot of supply ready to go as soon as we are able to -- as soon as we get regulatory approval. So that $3.5 billion to $4 billion is not really dependent too much on the sales outcome that will happen either way.

And maybe just to talk to longer term. So I think what we're suffering with this year is just an unpredictable market. So back to the prior question of the 35% to 40% or 60% to 65% gross margin. As it becomes more predictable, we will be able to order the right amount of material, you have the right amount of volume commitments that might not happen in 2024 as we've worked through some of our commitments. But we feel very confident in the overall 75% to 80% gross margin range in the long term.

Operator

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

Alec Warren Stranahan - *BofA Securities, Research Division - Associate*

This is Alec on for Geoff. Can you talk about all the other potential indications you may pursue for the INT vaccine? And how will you decide which indications to pursue first? Will this be based on the facts like rationale or an unmet need? And then secondly, what commercial hurdles do you expect for flu and RSV given the entrenched competition and new entrants respectively?

Stephen Hoge - *Moderna, Inc. - President*

Great. Thank you for the question. So first -- so obviously, we're moving forward to melanoma, as you know. And we're moving forward to non-small cell lung cancer. I think the opportunity there, the unmet need there is obviously very significant. And as we know, that's one of the largest opportunity for immune therapies generally. And so it's an obvious place for us to go next.

As we've said before, we have not yet publicly guided with our partner, Merck, on what the other indications will be, but we have said that we are going to follow the path of all the places where PD-1 KEYTRUDA have been successful, but where we think there is still headroom, still opportunity to significantly improve upon what's been achieved with the PD-1 antibodies. And so you can follow through the adjuvant settings as well as perhaps some of the Stage IV settings where there are those benefits and expect us to be moving there in short order. Ourselves in Merck are in the process of finalizing some of those plans and at the appropriate time, obviously, we will guide you on the start of those studies.

But rest assured, as we've said and as they've said before, there is a quite large program of studies that will be ramping up here in very short order and melanoma and non-small cell lung cancer are really just the first 2.

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

And I can take the question on RSV and flu. We are very excited to be launching RSV next year. So while we will be bringing the third product to market, we're very confident in what we believe is a best-in-class profile with our consistently high effectiveness across high-risk groups, thinking about our well-established safety profile in the only mRNA platform for RSV and lastly, as I mentioned earlier, being the only product with a ready-to-use pre-filled syringe. So we're feeling really good about the RSV launch preparations, and we're ready to execute in 2024.

From a flu perspective, we do think one of the advantages of 1010, which would be our first generation flu vaccine is our speed to market could give us an opportunity for better strain matching in the future. And as we get enhanced profiles for flu, as Stephen mentioned earlier, from a commercial perspective, we see a tremendous amount of interest in our combination vaccines both from patients as well as from health care systems.

So having RSV and flu gives us an incredible opportunity for combinations in the future.

Operator

Our next question comes from Evan Wang with Guggenheim Securities.

Boran Wang - *Guggenheim Securities, LLC, Research Division - Associate*

I just wanted some thoughts on COVID. And as we're thinking ex-U.S., any details you can share in terms of size orders and market positioning in some of your markets like Japan? And what could change in 2024? And in flu, just great to see the P303 study for enrolled. Just want some updated thoughts in terms of confidence on hitting on some of the B strain given some of the competitive updates?

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

So I'll take the first question. From an ex-U.S. perspective, we have signed a minimum commitment with Japan that has been announced. The minimum commitment that we signed with Japan is just to get product into the country as soon as August and so we're ready to execute this fall. If their vaccine uptake expands, we do anticipate additional orders coming in from Japan.

For the rest of the world, we have advanced purchase agreements that I have outlined already on in that first column as well as ongoing conversations with several other international markets, including those in the European Union.

In terms of 2024 changes. What we expect outside the U.S. is we expect more and more markets to actually be transitioning from central government procured to more of an endemic commercial market such as the transition that the U.S. is going through today. So we do anticipate changes. Most of those changes will be around shifting where the procurement is happening as well as changes in pricing and reimbursement going forward.

Stephen Hoge - *Moderna, Inc. - President*

The flu question. So yes, we're fully enrolled in P303, ahead of schedule on that and we will provide data shortly on the P303 study this quarter as we said.

As far as B strains goes, we already updated earlier this year that actually in the P302 study, we achieved non-inferiority in the B strains. You'll remember in the P301 we just -- we had missed that. And so we were learning as we went. And we actually made a series of changes into the P303 study that we were confident and remain very confident, we'll provide a benefit in the B strains that will improve immunogenicity there.

So I remain quite optimistic that our understanding of science is really strong, we think best-in-class and that where we will be and when we look at that P303 data, ensure is in a very strong position as it relates to B strains and continue to be in a very strong position as it relates to the A strains.

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

And Kevin, we will take our last question.

Operator

Our last question comes from Simon Baker with Redburn.

Simon P. Baker - *Redburn (Europe) Limited, Research Division - Head of Pharmaceutical Research*

Just 2 questions from me. One was, how has your view of the RSV opportunity changed in light of compared to 2-year data and the ACIP recommendation. In what regard do you think that you can achieve best-in-class profile? And the second question was just a little bit more about the CMV Phase III enrollment and if you think you'll be able to get full enrollment by this quarter?

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

I'll start with the RSV question. In light of the ACIP shared decision-making recommendation as well as some of the data that was shared this year around revaccination, we do anticipate a slower vaccine uptake at the start. In terms of our potential in that market, we do continue to be very confident that we have a best-in-class profile. And as we get additional data from our own vaccine program, we are hopeful that the ACIP recommendation will be broadened and could be -- will enable a faster uptick in outer years.

Stephen Hoge - *Moderna, Inc. - President*

And the only thing I'd add to that in terms of the development side is we are obviously looking at multiple different versions of RSV combination vaccines and 1 of the advantages there will obviously be increased convenience and compliance. And that's where if we can create health care system value, I think it will be -- it will continue to evolve the recommendation that people have around that.

As it relates to CMV, so we haven't set out a guidance on when we would expect the enrollment to complete. But we are actually confident given the trajectory that we're already past 80% that we will complete enrollment this year, I'm not saying this quarter, but this year. And as I said, what really matters is probably not whether we're at 80% or 99% or 100% enrollment, it's the accrual of cases and events that will drive the first interim analysis from forward. Now obviously, more patients, more participants enrolled will increase the number of and pace of those events over time. And so we are focused very much on that operationally, and we do hope to have that completed this year.

Operator

I'd like to turn the call back to Stéphane for any closing remarks.

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

Well, thank you very much for your questions. We look forward to seeing many of you in the next days and weeks, but especially seeing you at the R&D Day on September 13 to see many of you in person. Have a great day. Thank you.

Operator

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