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OVERVIEW:

Company Summary

REFINITIV

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PRESENTATION

Operator

Good morning. My name is Kevin, and welcome to the Moderna's Third Quarter 2023 Earnings Call.

(Operator Instructions)

Please be advised today's call is being recorded. At this time, I'd like to turn the call over to Lavina Talukdar, Head of Investor Relations at Moderna. Please proceed.

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

Thank you, Kevin. Good morning, everyone, and thank you for joining us on today's call to discuss Moderna's Third 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 Stephane 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'll turn it over to Stephane.

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

Thank you, Lavina. Good morning or good afternoon, everyone. Thank you for joining us today. I will start with quick review of our business for first quarter. Arpa will then give you an update on our commercial progress and plans. Jamey will present our financial results and will explain in detail the onetime charges we announced this morning in our press release. Stephen will then review our clinical programs. And I will share our

key priorities for 2024 and 2025 to return Moderna to sales growth and profitability. We delivered $1.8 billion in Spikevax sales of COVID vaccine in the first quarter. Based on trends we are seeing in the U.S. COVID market in recent weeks. We expect our sales for 2023 to be at least $6 billion.

We have been preparing for the 2023 for COVID launched throughout the year because the U.S. market was pivoting from a pandemic government purchase market to a commercial market. I am very pleased to report that according to IQVIA market data, we have a market share in the U.S. for 45% season to date compared to 36% for 2022. And data will show you, we even achieved a 51% market share last week in the U.S.

This commercial performance in the U.S. market shows that Moderna can compete commercially with large established players. That will prove important as we launched RSV 2024, a combo of flu/COVID 2025. On the cost side of the company, we informed you at R&D Day that it was important for us to refile our manufacturing footprint as the world has moved from a pandemic to an endemic setting. I am pleased that our manufacturing and finance team were able to move fast and recycle manufacturing so that we can go back to 75% to 80% gross margin levels. This residing resulted in a charge of $1.6 billion, which Jamey will explain in detail in his section. Now let me turn it over to Arpa to walk you through our progress in the U.S. market.

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

Thank you, Stephane, and good morning or good afternoon to everyone. Today, I will provide an update on our third quarter performance, our U.S. commercial launch progress and our preparation for our RSV launch next year. Our total sales in the third quarter came in at $1.8 billion, which includes approximately $800 million in international sales and $900 million in U.S. sales. Total sales for the first 3 quarters of the year were $3.9 billion. Turning now to our expectations for the fourth quarter and full year 2023 outlook.

In our international business, we expect an additional $1.1 billion in sales. These sales are based on government contracts and once vaccine doses are shipped and accepted by the customer, they are not returnable. More than half of these sales have already shipped in the fourth quarter. In the U.S., we expect at least $1 billion in sales in the fourth quarter, which would bring U.S. sales to approximately $2 billion for the second half of 2023. This assumes approximately 50 million doses administered in the U.S., which would be similar to the fall season of 2022. With the $3.9 billion in sales recorded as of the end of the third quarter, expected fourth quarter sales of $1.1 billion internationally and at least $1 billion in the U.S., our updated sales outlook for 2023 is at least $6 billion.

Now turning to the U.S. launch. The data shown here are from IQVIA. As a reminder, IQVIA data only captures the retail channel in the U.S., which includes retail pharmacies and long-term care. I'm first going to share what our weekly market share trends look like and then discuss our cumulative shares since launch and how it compares to last year. On the fifth week post launch for the week ending October 20, what you can see on the slide here is that Moderna's market share is 51%. As we look over the season to date, Moderna's cumulative market share for this season is now 45%, which is higher than the 36% market share we had in 2022. As Stephane mentioned, this progress demonstrates our ability to compete effectively in the commercial endemic market.

Turning now to Slide 8, which shows cumulative vaccinations in the U.S. retail pharmacy channel. This year, COVID vaccines were launched 2 weeks later than in 2022. As a result, we analyze the data on a launch adjusted basis, as shown in the graph on the slide. To do this, we look at the data based on the number of weeks post launch, rather than simply on a calendar basis. This helps us compare vaccines uptake in 2023 versus 2022.

On the graph, the blue line represents cumulative vaccinations post launch in '22, and the red line represents cumulative vaccinations post launch this year. And on a launch adjusted basis, the total market is tracking ahead of last year's vaccination levels both on a weekly basis, but also on a cumulative basis. As a reminder, the retail channel is typically the largest segment, so these trends in the first 5 weeks are encouraging given the later launch and slightly shorter season in 2023.

Let's now turn to look at the channel mix in the market on Slide 9. In 2023, we expect retail and non-retail mix to evolve as the season progresses. The non-retail segment includes independent networks, health systems, U.S. government entities, clinics and other providers. Last year, this nonretail segment met up approximately 16 million doses in the season or 33% of the total market. The gray line on the graph chart CDC reported vaccinations, which capture both retail and non-retail channels in 2022. The blue line is vaccination that retail pharmacies as reported by IQVIA in 2022. The difference between these 2 lines represents the non-retail segment.

Looking at the data on the graph, you can see that the retail channel captures the majority of vaccinations early in the season. This can be seen in the narrow spread between the CDC and IQVIA data represented by the gray and blue lines, respectively. Now if you look at the seventh week of launch in 2022, the current week that we are in, in '23, you can see that the slope of the non-retail channel is increasing. We know that distributors this year have recently increased shipments to the non-retail channel, and as such, we expect non-retail as a percentage of market to grow between now and year-end. Importantly, we expect our market share to be consistent across channels and higher in 2023 than in 2022.

We are committed to focus on public health efforts to increase vaccination rates. In the United States, we are taking a multipronged approach to educate all stakeholders and increase the urgency to get vaccinated. Across the medical community, pharmacies and clinics and advocacy groups, we are providing patient education resources to help our partners encourage their patients to get their COVID vaccine this fall.

Earlier this week, we also launched our branded direct-to-consumer campaign both on TV as well as across digital channels. For the remainder of the year, we will be amplifying education on the need for vaccination prior to gathering particularly with at-risk populations such as families and traveling during the holiday season. We are also launching a focused education effort for consumers who are infected with COVID this summer, on the importance of getting vaccinated in November and December.

To summarize our COVID outlook, we expect at least $6 billion of sales this year, based on the U.S. vaccination trends that signal a market of at least 50 million doses. Moderna's share, both in retail and non-retail, is expected to be consistent across channels and higher than in 2022. Vaccine administration from the retail channel are tracking ahead of last year on a launch adjusted basis, signaling strong early consumer demand.

Last year, only about 55% of COVID vaccinations were given by the end of October, with an additional 23 million vaccinations given in November and December. We expect the non-retail channel to increase as a percentage of the market, which will provide additional sites of vaccination for consumers to allow for a strong November and December. This year, given the later launch of vaccines, the non-retail channels are just now beginning their vaccination campaigns. To continue the momentum from our launch and supplement our customers' efforts, we will be amplifying our marketing campaigns in November and December. Let me now turn to the upcoming RSV launch in 2024. We believe we have a best-in-class product profile that can make a difference both to patients but also to our customers.

Our clinical profile shows strong vaccine efficacy. We have a well-established safety and tolerability profile that leverages the same mRNA technology that has been delivered in over 1 billion COVID vaccines. Additionally, we have not seen any cases of GBS in our Phase III trial. An important differentiator for our customers is that we will be the only company with ready-to-use prefilled syringes, which are preferred by pharmacists and by clinicians. We continue to expect a 2024 launch of our RSV vaccine in the U.S. and are also preparing for launches in several international markets. We're encouraged by the recent RSV launches in the market this year, beating expectations due to robust consumer awareness and demand.

And we believe that we are well positioned for our launch in 2024. Our strong clinical profile and ready-to-use prefilled syringes are key competitive differentiators. My team and I are particularly excited about our ready-to-use prefilled syringes, given the robust demand for our COVID prefilled syringes this fall.

The majority of RSV vaccines in the U.S. will be given in the pharmacy setting. And given the ongoing pharmacy labor shortages, our ready-to-use presentation will save time and also reduce administration errors. We will be the only company with a one-step administration compared to competitive products, which require multiple preparation steps by pharmacists and clinicians. We are very excited for the launch of our RSV vaccine given the strong product profile. And the commercial team is well positioned to bring our RSV vaccine, our second respiratory vaccine to market. I will now turn it over to Jamey to provide an update on our financials.

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

Thanks, Arpa, and hello, everyone. Today, I will review our financial performance for the third quarter and provide an updated framework for our full year 2023 financial outlook. Additionally, given we know it's top of mind for investors, we wanted to provide our early thoughts on 2024 and how we're approaching the next couple of years.

Starting on Slide 15. Total net product sales for the quarter were $1.8 billion, down 44% year-over-year driven by lower sales volume and partially offset by a higher average selling price. Product sales were almost evenly distributed between the U.S. market and the rest of the world. We initiated product shipments to customers in mid-September for the fall booster season, following the authorization of our updated COVID-19 vaccine. Cost of sales for the third quarter of 2023 was $2.2 billion compared to $1.1 billion in the prior year. I will provide a detailed commentary on the following slides. Research and development expenses were $1.2 billion, which increased by 41% versus the prior year. This increase was driven by our expanded and maturing development pipeline with 6 products now in Phase III studies or pending approval.

Selling, general and administrative expenses were $442 million, reflecting an increase of 59% year-over-year. The growth in spending was primarily driven by the build-out of our commercial activities and in particular, our launch in the U.S. commercial market. The income tax provision in Q3 was $1.7 billion, as we reported a valuation allowance against deferred tax assets of $1.7 billion.

Under GAAP accounting rules, we are required to take a reserve, also referred to as the valuation allowance for deferred tax assets when the current year and cumulative income projection for the next 3 years is in a loss position. These losses indicate our deferred tax assets may not be fully realized. It's important to note future income from products not yet approved by regulators are excluded from these income projections, which restricts us to just our COVID vaccine, and it does not include expected future launches. In combination with our updated endemic COVID forecast, we determined it was appropriate to record a valuation allowance for our deferred tax assets. This valuation allowance does not impact cash flows nor future returns, nor the company's ability to utilize deferred tax assets in future periods.

Net loss for the period was $3.6 billion compared to net income of $1 billion last year. Diluted loss per share was $9.53 compared to diluted earnings per share of $2.53 in 2022. Finally, we ended the third quarter with $12.8 billion in cash and investments, the decline versus prior quarter was driven by our operating loss and sales to be collected in Q4.

Now let me come back to cost of sales on Slide 16. We now expect full year cost of sales of $5 billion driven by $1.5 billion of unit-driven expenses, which also includes royalties and $3.5 billion of inventory write-downs and charges related to CMO purchase commitments, cancellation fees and wind-down costs. As Stephane previously highlighted, in our pursuit to optimize the cost structure of our COVID-19 franchise, we undertook a strategic initiative in the third quarter to restructure our manufacturing footprint, which was built for the pandemic. As part of this initiative, we reduced our capacity and commitments with several third-party vendors. We reevaluated our raw material inventory levels and cut back on our purchase commitments for raw materials not anticipated to be consumed before expiration.

As a result, we are reporting charges of $1.6 billion, $1.4 billion of which are in Q3 and an expected $0.2 billion in Q4. The $1.4 million charge in Q3 consists of inventory write-downs of $0.9 billion and CMO wind-down costs and cancellation fees of $0.5 billion. The Q4 charge is related to CMO wind-up costs. Despite the immediate financial impact, we are confident that this strategic move will improve the efficiency of our manufacturing operations and establish a strong foundation for improved margins going forward. As part of the $1.6 billion in total restructuring charges I just mentioned, only the CMO related costs and cancellation fees are cash restructuring costs. We project this approximately $0.7 billion charge will have a payback in less than 2 years and a net cash benefit of approximately $1 billion through 2029. As I mentioned, our full year forecast for cost of sales in 2023 is now $5 billion before resizing charges of $1.6 billion.

Our cost of sales for the full year is expected to be at the low end of our previous guidance of $3.5 billion to $4 billion. So now coming back to my commentary on Q3. In addition to unit-driven manufacturing costs and the cost in this initiative, we also incurred approximately $0.4 billion of inventory charges for excess and obsolete material, demand-related write-downs of our latest Spikevax product and unutilized manufacturing capacity charges.

Moving to Slide 17. In summary, we made substantial progress to resize our COVID cost structure and accelerated our path towards our longer-term target of 20% to 25% of sales. We expect our cost of sales to not only be at a lower level, but also to be more predictable in the future. In recent quarters, our cost of sales were highly impacted by write-offs and charges as we just addressed today and in previous calls, year-to-date write-offs and charges for inventory CMO and supplier-related commitments are 74% of sales.

Starting in 2024, we expect those to be less than 10% of sales on an annualized basis. Our capacity is now better positioned to scale with volume. At $4 billion sales level, we expect cost of sales of approximately 35%, reducing to approximately 30% and $6 billion of sales and 20% to 25% at

even higher sales levels. In other words, with our resized manufacturing footprint, we now expect to achieve significant volume leverage moving forward.

Let's now move to Slide 18. While we intend to continue to focus on GAAP results, we wanted to give you a view of our financial results in Q3 with and without the resizing and tax valuation allowance charges. While our total GAAP net loss in the third quarter was $3.6 billion, our loss excluding these charges would have been $0.5 billion.

Now let's turn to our updated 2023 financial framework on Slide 19. As Arthur mentioned earlier, we now expect product sales for 2023 of at least $6 billion for the full year, which is comprised of $3.9 billion of sales through the third quarter, an additional $1.1 billion of international sales in Q4 and at least $1 billion of Q4 sales from the U.S. As explained earlier, we now expect cost of sales for the full year of approximately $5 billion which includes resizing charges of $1.6 billion.

For R&D and SG&A, we now expect full year expenses to be approximately $6.3 billion, with approximately $4.8 billion in research and development. Our R&D spend is slightly higher than the $4.5 billion previously forecasted, which is mainly driven by business development activities as well as additional investments in our late-stage clinical trials. Our forecast for SG&A expenses remain consistent at approximately $1.5 billion. We now expect a full year tax expense of approximately $0.8 billion to $1 billion driven by the $1.7 billion increase in the deferred tax allowance I referenced earlier. And finally, we now expect capital expenditures of approximately $0.9 billion, down from our previous guidance of $1 billion.

Before I get into the specifics on 2024 and 2025, I wanted to share with you our principles on how we are operating the company today on our plans over the next 3 years. We are laser focused on making our COVID franchise profitable in 2024 and beyond. We look at our Spikevax product profitability, excluding research and development costs for our future pipeline, and we believe our recent resizing efforts will ensure that our COVID franchise is a continuous and increasing source of income and cash generation. At the same time, we also recognized a significant and unique opportunity for organic sales growth ahead of us with our late-stage pipeline. We will be disciplined in our investment approach and adjust R&D and SG&A based upon the sales performance of our product lines, which in 2024 is still mostly COVID, but we expect it to also include RSV.

We expect this investment in our late-stage pipeline will result in a loss over the next 2 years, but help us to just break even starting in 2026. We believe our current balance sheet is more than sufficient to fund our plans without the need to raise equity. We are also not planning to repurchase shares in the intermediate term. Stepping back, we believe this is an unparalleled opportunity to impact the lives of patients while creating shareholder value at the same time.

Moving to Slide 21. Let's start with our view on sales over the next couple of years. We are expecting sales to hit a low point in 2024 at approximately $4 billion. The biggest change year-over-year is related to our signed APAs. We currently have $1 billion of COVID-related APAs for delivery in 2024. Recall that our first half sales in 2023 of $2.1 billion were mostly deferrals from our 2022 existing contracts. So we expect minimal sales in the first half of 2024.

For the U.S., we expect 2024 to be at least $2 billion and believe it will grow over time. Lastly, we expect approximately $1 billion from RSV and other international COVID sales. And finally, in 2025, we expect to return to growth. Let me finish by giving you a more fulsome view on 2024 and our thinking on 2025.

Starting with 2024. As I just explained, we expect sales to be approximately $4 billion. Cost of sales are expected to be approximately 35% of sales, R&D expenses of approximately $4.5 billion in 2024 would be down 6%. In 2024, the majority of our R&D expenses are for registration trials, which are now mostly committed. I will speak to our view on 2025 R&D expenses in a moment. SG&A expenses of approximately $1.3 billion in 2024 would be down 13%. We expect taxes to be negligible in 2024 and capital expenditures to be similar to 2023 at $0.9 billion.

In summary, for 2024, Spikevax will generate nearly $1 billion of income. When we combine that with our estimated investments in R&D and capital expenditures, our cash balance is projected to be approximately $9 billion at the end of 2024.

Now for our preliminary thoughts on 2025. As mentioned earlier, sales will return to growth. Cost of sales will improve with the increased sales growth. R&D will be flat to down, and we have much greater flexibility for reduction, given that only approximately half of our current R&D spending levels for registration of trials are committed for 2025.

SG&A will be flat to down, taxes will continue to be negligible, and capital expenditures will be materially lower after the completion of our facilities in the U.K., Canada and Australia in the first half of 2025. In summary, our COVID operating income will grow and our investments will remain flat or lower leading us to an estimated ending cash balance of approximately $6 billion to $7 billion in 2025. Finally, during this period, we expect to launch 5 new products to help us break even in 2026. So with that, I'll now turn the call over to Stephen.

Stephen Hoge - *Moderna, Inc. - President*

Good morning or good afternoon. Today, I will do a quick review of our clinical programs. Many of the details from these programs were shared at our R&D Day in September. I will also review the Phase III trial designs for our combination flu and COVID vaccine, mRNA-1083 and the Phase III trial design for our INT in non-small cell lung cancer. During R&D Day, we shared the significant progress we've made through the year in advancing our late-stage pipeline, creating the opportunity to have up to 15 product launches in the next 5 years through 2025 and subject to regulatory review and approvals, we anticipate launches for our RSV vaccine, our flu vaccine, a next-generation COVID vaccine and our combination flu and COVID vaccine.

Looking beyond 2025, we have a diverse pipeline of other vaccines, cancer therapies and rare metabolic disease medicines. We're very excited by the potential benefits, these medicines offer across a diverse range of therapeutic areas. Slide 25 is an overview of our respiratory vaccines pipeline. Our leading pipeline includes commercial and Phase III programs against COVID, RSV and flu as well as earlier-stage next-generation programs in COVID and flu and multiple illuminations. We recently shared positive top line Phase I/II data from our combination flu and COVID vaccine, mRNA-1083. And on the heels of this success, we've started and are rapidly enrolling a Phase III study for mRNA-1083 in adults 50 and older.

Slide 26 shows the Phase III design for mRNA-1083. The Phase III study is a randomized, stratified, observer-blind, active control study, evaluating the immunogenicity and safety of 1083 compared to co-administered flu and COVID vaccines. The study will enroll 8,000 participants overall, with 2 cohorts of 4,000 participants stratified by age 65 years and older and 50 to 64 years of age.

Both cohorts will receive mRNA-1083 or in a control arm, an age recommended licensed quadrivalent flu vaccine plus our approved COVID vaccine. Study participants will be followed for 6 months.

Now next on Slide 27 is an overview of our latent and other vaccines pipeline. As previously announced, our Phase III in vaccine efficacy and safety of our CMV vaccine in women of child-bearing age is now fully enrolled, including the adolescent cohort. The study is accruing cases, and we look forward to vaccine efficacy data when it becomes available. Earlier-stage clinical programs against EBV, HIV, VZV, HSV and against Nororovirus and Lyme disease continue to progress.

Slide 28 is an overview of our therapeutics pipeline. We're proud of the progress across cancer, rare diseases and other areas. Many of the details of these programs were highlighted at our recent R&D Day, and I refer you to that presentation on our website. Notable since R&D Day is the continued rapid enrollment of the INT Phase III adjuvant melanoma study, which has seen a great deal of interest from investigators and patients since presentation of the Phase II data at ASCO earlier this year.

As previously announced, before the end of the year, we will conduct another analysis of the Phase II study with longer follow-up time at approximately 3 years, and we are looking forward to sharing that data. INT is also moving forward in other types of cancer with the initiation of a second Phase III study in adjuvant non-small cell lung cancer. The Phase III design for adjuvant non-small cell lung cancer is shown on slide 29. It is a randomized placebo blind -- double-blind, placebo and active comparator controlled study of a combination of INT plus KEYTRUDA versus placebo plus KEYTRUDA in patients with non-small cell lung cancer.

The study will enroll approximately 900 patients with Stage II to IIIB tumors who were resected and previously treated with adjuvant chemotherapy. Each patient will receive up to 9 doses of INT administered intramuscularly every 3 weeks with KEYTRUDA administered every 6 weeks in the active

arm or 9 doses of a placebo injection administered every 3 weeks and KEYTRUDA at every 6 weeks in the comparator arm. The primary endpoint of the study is disease-free survival. Key secondary endpoints include overall survival, distant metastasis-free survival and patient-reported outcomes. This study marks an important milestone in our collaboration with our partner, Merck, and our shared commitment to rapidly bring INT to patients.

With that, I'll turn it over to Stephane.

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

Our focus is to return Moderna's sales growth and profitability. To achieve that, we have 3 priorities, priority number one, commercial execution. Our market share in the U.S. demonstrates we can compete. We are focused on launching RSV in 2024. We believe we have best-in-class profile for RSV vaccine, high-efficacy, good safety profile and the easiest to use in pharmacies or doctor's office. As you know, pharmacy chains are in challenges given the workload, especially in the fall seasons. The 2 of vaccines on the market today are very complicated to prepare before injection; one is nine steps and one is four steps. Now we launched pre-fille syringe and, as Arpa said, we're very excited about that. And from the discussion that has with the leadership of pharmacies, I believe that this will be an important differentiation.

Our commitment to combo vaccine should work in 2025. And as you know, flu is a higher volume market than COVID. In the U.S., for example, flu is around 3x the number of doses compared to the COVID market. We these new product launches in '24, '25 and the combination of COVID sales in the endemic setting, we believe Moderna will be in sales growth again in 2025.

Priority number two, disciplined investments. We'll be disciplined in our investments and cycle them based on our sales performance. As you saw, we have taken bold actions, we signed our manufacturing footprint in the third quarter. The team is not done, and there are many continuous improvement projects to drive a reduction in cost of manufacturing. We also look at our R&D costs and we consider partnering some programs, if needed, to allow us to be responsible and disciplined about our costs.

For SG&A, as Jamey mentioned, we are currently going through our 2024 budget and our goal is to have a lower spending SG&A 2024 than we had in 2023. We still plan to keep SG&A flat in 2025 versus 2024. We are launching respiratory products in 2024 and 2025 and we anticipate the same teams we sell them. We also expect productivity gains as we improve our commercial operations.

As Jamey mentioned, we expect to break even in 2026. Priority number three. Executing on our late-stage pipeline to drive sales growth. As you all know, we have an exciting late-stage pipeline with 6 Phase III assets. For respiratory programs, RSV, flu, NextGen Covid, mRNA-1283 and COVID plus flu combo that Stephen just spoke about. One Latent program CMV, which is fully enrolled in its Phase III and accruing cases. One Oncology program INT in melanoma and as Stephen mentioned, in lung cancer.

We look forward to having and sharing 3 year of INT data from a melanoma study before the end of this year. If the data are strong, we believe it will be the basis for regulatory discussions for potential activated approval. We have been investing in building a factory in Marlborough, Massachusetts to enable the commercial launch for INT. Thanks to the mRNA platform with this, we have an exciting pipeline with up to 15 launches in the next 5 years. We are the largest late-stage pipeline of mRNA company in the world, and we'll continue to focus to deliver the greatest possible impact to people for mRNA medicine. I've never been more excited about the potential we have to deliver for patients. The actions we are taking help us to execute on that vision. With this operator, we'll be happy to take questions now.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question comes from Huidong Wang with Barclays.

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

I have 2 questions regarding the commercial questions. First, you did mention in 2026, you're looking to have a breakeven. And when we take a quick look based on your 2024 and 2025 outlook, it seems the total cost could be in the $8 billion to $9 billion that range. Could you give us a sense what could be the additional sales if we're using 2024 guidance as a base point? And the second very quickly regarding the manufacturing resizing. After resizing, what is the full capacity regarding doses? And what percentage of the manufacturing will be internal in 2024 and 2025?

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

Maybe I'll take the first one for a further question. So in terms of 2026, thanks for the question. Let's talk about how we're thinking about it. So we mentioned $4 billion in 2024, approximately $4 billion. And this is all about our late-stage pipeline coming to fruition. So in 2024, we'll launch RSV, it's mostly kind of in the second half year sales, and then we'll have a full year of 2025, so that will provide growth. We will also come to market with flu in 2025.

We'll also come to market with the combination of flu and COVID in 2025. Again, it depends on timing. But by 2026, we should have a full portfolio. We're not going to say what the exact sales numbers are, but you mentioned $8 to $9 billion in costs, not exactly sure where you get there unless you're assuming a certain sales line on that. But let me go back to what we tried to lay out here. If you assume, for instance, $6 billion of sales, we should have 30% of costs or $8 billion of sales, we should have 25% of cost. And then we've said historically at our R&D Day that we need $25 billion overall to make this investment, which should average $5 billion a year.

So hopefully, we're giving you enough pieces without officially guiding any kind of numbers in 2026. But here's what's also important is if those sales, don't come to fruition we are telling you that we will adjust our expenditures in our investment. So that's -- we hope that we are -- they will, we are confident in our pipeline, but should it not happen, then we were prepared to adjust our investment. I missed the second part of the question. Can you maybe repeat the second part of your question, I apologize, I missed it.

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

Basically after manufacturing resizing, what is the full capacity regarding doses? And then what percentage will be internal?

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

So -- as we try to lay out here and are showing you this capacity is built for volume leverage. So we at least put $10 billion of sales on that page, and it will require no additional capacity. We will complete of course, over the next 1.5 years, the U.K. facility, the Canada facility and Australia facility. But for the respiratory framework, we need no more, at least $10 million. I won't project beyond that, but that should answer that question. INT is little bit different, and we are building that and getting that ready for commercial purposes, but we're built for volume leverage moving forward.

Operator

Our next question comes from Salveen Richter with Goldman Sachs.

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

Two for me here. One is you provided guidance of about $4 billion between COVID and RSV. On the forward here for 2024. Could you just speak to the contribution from each and how you're thinking about flu monotherapy and the second question is that your financial framework for 2025

includes the ability to flex R&D and SG&A. And are there any parameters you can share on the range of this flexibility and how you would prioritize R&D programs in development?

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

So on the $4 billion, we're not going to break out the $1 billion that we attributed to RSV and COVID. All we can say is we've talked about our PDUFA date and that we filed and see a certain amount of countries across the globe. I will also say, as I mentioned in her prepared remarks that we are super confident in the product profile. We are encouraged by the market and how it's already started from an uptake perspective, and we think we will compete very well.

(technical difficulty)

and beyond. As it pertains to the flexing on our spending for 2025, obviously, I don't know, 80% of our expenses or investments are in R&D, so $4.5 billion for R&D and $1.3 billion for SG&A. So that, as I mentioned, 50% of the current spending levels is not committed. So we have time to make decisions and watch the market to be able to say what amount of registrational trials and what amount of R&D are we going to spend in 2025. So hopefully, that gives you a sense for how much is still the ability to flex. We also have other levers that we can pull, et cetera. SG&A, we also have some flexibility, probably not to the same magnitude, but there's still some amount of flexibility to bring that down from a variable expense perspective.

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

And Savi, this is Stephane, maybe just to add to Jamey's point on the R&D, as I mentioned in my remarks, if we have to, we would be open, of course, to partnerships some of those programs, which is an important way we reflect the early number based on where the sales are as Jamey mentioned, which is if sales offering to our plan that we're going to be okay. If the sales are below, we will be very open to partnering us. We've done that in the past, the team knows how to do it, but we will be disciplined about our investments in the business based on where the sales line is.

Operator

Our next question comes from Eliana Merle with UBS.

Unidentified Analyst

This is Sarah on for Eliana. First, I guess, can you talk about in 2024, again, on that $1 billion RSV international sales number. Are you expecting any contribution from flu in '24 and maybe how you're thinking about it into '25. And then on CMV, can you talk about where you are in cases and how they're tracking versus R&D Day, where I think you said 1/4 of them were currently tracked, that would be great.

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

So thanks, Sarah. I'll take the first part and then hand it over to Stephen on CMV. So there is no flu contribution in our 2024 sales outlook of approximately $4 billion. So in that $1 billion or that is solely RSV and other COVID international sales. We do, as I mentioned into answering Salveen's question. We do expect to launch flu in our combination products sometime in 2025, and we'll see what we've projected at that time.

Stephen Hoge - *Moderna, Inc. - President*

And on the CMV question, thanks for that. So yes, we did update that we're about a quarter away through the case accrual back in R&D Day. I think the next -- we continue to recruit case at a steady pace. I do think the next update will provide is likely our vaccine's day in the spring.

Operator

Our next question comes from Terence Flynn with Morgan Stanley.

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

I know GSK has provided an estimate in terms of size of the RSV market about GBP 5 billion and Pfizer has given some metrics as well. Given what we're seeing now with these early launches, can you provide us with your assessment of total market size here? And then given some of your comments on competing with larger companies as you're doing in COVID now, where ultimately do you see your market share shaking out in the RSV space.

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

Thank you for the question. In terms of the total RSV market, as I mentioned earlier, we're excited by the uptake and the consumer awareness of the market overall. And our projections are similar to what both GSK and Pfizer have already guided. In terms of our market share with RSV, we have not yet provided or are ready to provide any forward-looking projections on share. But we are very excited about our strong product profile both in terms of efficacy, safety. And as I mentioned, are ready-to-use prefilled syringes. So we will be leveraging the learnings and the success from our COVID commercial launch this year and applying them to RSV next year.

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

Yes, Just to add to Arpa, Terence, it's Stephane. The point that Arpa and I made about the market share of COVID is what I think is very important. I think some people believe that because we are a new company in commercial, we're not able to compete and I think the market share data that Arpa shared show that is able to compete, and we will continue to improve things that we are doing because we're not only improving the start of our culture, as you know but the share already moving from 36% last year to 45% cumulative so far in the season.

I think it's already a demonstration of what the team is able to achieve. And the season is not over, so I see that 51% so let's see what this was finished when the season is over. But basically, the defection we have, as I mentioned, have been speaking to pharmacies leadership, and they are all I think a very big workload issue, as you know, we have been tracking some pharmacy chains in the U.S. as we speak. And you think about the season, there to report the normal business of pharmaceutical preparations and then the flu and then the COVID and then RSV and as I mentioned, those 2 of our products, if you just download the label of those products from FDA website, then you look at how many steps they have. It's a very complicated and we talk to pharmacy leadership. They don't know how they're going to deal with that type of workload. And so coming with pre-filled syringe is a tremendous differentiator and we have very good efficacy with a very good safety profile. We really believe that we have the best-in-class product in the market and that means if you don't commit it is going to translate into a very good effect.

Operator

Our next question comes from Jessica Fye with JPMorgan.

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

Just a couple coming back around to one that I think some others were trying to get at, but maybe a little differently. What we think about breakeven in 2026, what are you contemplating in that sales number embedded in your assumption? Does it reflect just respiratory vaccines? Or are you considering INT could be on the market then? And then second, I know you said the percentage of non-retail jobs would grow as the season progresses from where it has been so far this season. Do you believe that the proportion of COVID shots running through the retail channel has shifted at all bigger picture in 2023 relative to 2022? Or should we think of that proportion as remaining similar year-over-year?

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

Again, without getting in too much detail on 2026 in terms of how we think about it. I mean the best way to keep going back to that late-stage pipeline that we've been talking to you about RSV, flu, our combination, our next-gen COVID product as well, will all be very much there for the year of 2026 and we are confident in all those product profiles and how we will compete. As I mentioned, at 6%, our cost of sales at $6 billion, sorry, our cost of sales would be 30% at $8 billion, our cost of sales will be 25%. And of course, we'll try to improve on that. And that will give us the envelope for how much we can continue to invest. In the future products, which we said we'll launch 15 by 2028. That will be all of our latent portfolio that will be our INT portfolio. That will be our rare disease portfolio. So I think that's as much as we can say right now. I just want everybody to know that we are very committed to breaking even in a year, and we have a lot of flexibility, both from a growth standpoint and a disciplined investment standpoint.

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

And I can take the second question on the percentage of non-retail. So as expected, in 2023, the retailers has been the majority of the market with more than 90% of the volume during the first few weeks. However, we're now beginning to see a shift towards more non-retail channels, as I had mentioned. We are seeing increased shipments to IDNs, to clinics, to pediatricians as of the recent weeks. And as I think about full year 2023, I believe the retail mix will be stronger than in 2022 and could land at about 70% to 80% of total vaccinations whereas in 2022, we saw that the retail channel was only about 2/3 of the mix.

Operator

Our next question comes from Luca Issi with RBC Capital.

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

Maybe circling back on the P&L. I appreciate all the effort on resizing manufacturing and the focus on gross margin. But how should we think about OpEx plus CapEx as COVID numbers continue to come down. We've seen BioNTech and Pfizer materially realigning OpEx plus CapEx to their top line. I believe BioNTech lowered by $600 million this year and Pfizer by $1 billion this year and $2.5 billion next year. However, your OpEx plus CapEx has not materially changed this year and you anticipate that the next year is going to be generally flat to down. So can you just maybe comment on why you think that's the right strategic decision for the organization?

And then maybe second question on RSV, obviously, impressive initial launch by GSK and Pfizer and the differentiation of your product, but what's the latest thinking on whether the vaccine is needed every year or less frequently than that. Is there a scenario with Pfizer and GSK penetrated market pretty aggressively this year and then you face an uphill battle next year as it turns down that you need a vaccine maybe every other year and not every year? Any thoughts there, much appreciated.

Stephen Hoge - *Moderna, Inc. - President*

Maybe I'll take the first -- the second part of that question and then hand it over to Jamey for first. So on RSV and the need for it, obviously, we're continuing to follow the public health situation in terms of the rate of occurrence RC epidemic this year. At this point, I think we don't have data yet on whether or not it will ultimately be an annual or something less than annual, say, every 2- or 3-year vaccination regime. I think like everybody else, we'll be looking to our data, the other manufacturers' data as well as the public health, the epidemiologic data to guide that decision.

There are plenty of vaccines for which there is an approach flu as an example, where there's a seasonal vaccination approach, both because of the benefit offered by the vaccine, but also because of the convenience of just making sure that every season, every year, people are reminded to get that vaccine. So the ultimate decision on whether this is going to be recommended is not ours to manufacture, all of public health officials based

on a number of factors, which will include the EPI and the data we'll provide but other factors as well and we'll work to make sure they have the data they need to make that decision.

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

And I'll take the first part. Thanks, Luca, for the question. I think the short answer is the opportunity set ahead of us, and we are acting. So you referenced some of our competitors, I just want to break that down. We are super encouraged by the opportunity for additional growth and our ability to impact patients. And we have this 15 products that we think will launch by 2028 or by 2025. And we think that's the right thing to do. We have to grow out of our -- we have to grow this company and to be able to afford the investments to be able to capture the unparalleled opportunity for this. And I think we are acting.

I believe we are acting. I think I mentioned everything that we're doing from a cost of sales perspective. And so I think that is very much in line and sized appropriately to have volume leverage when it comes because it will come. And we are saying in 2024, we can adjust both R&D and SG&A down to a good level, down 6% R&D, down 13% also on SG&A. We are largely committed to our registrational trials for 2024. So as I mentioned, we don't have as much flexibility in that particular year. But by 2025, we have even more flexibility. So we're prepared to take action should we need to, but we're very optimistic about the pipeline that's coming. And hopefully, this is coming through growth and we'll still be able to afford much of this investment.

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

Yes. I'm Stephane, just maybe adding to Jamey, who said it super well. As you know, we have a platform company. And the profitability of technical success of those programs, we feel very good about. If you just look at with COVID and Phase III RSV -- sorry, and Phase III for RSV and Phase III for flu, we have 3 out of 3 positive Phase III. This is not your industry average. So we think we can create value, increase return on capital for shareholders by investing that capital through high-quality projects that are in late search pipeline. As I said, we have the largest late-stage pipeline of any company with 6 programs right now. And as soon as the (inaudible) which is very, very soon, there's going to be 7 programs. We believe the best way to create results for our shareholders is to invest that capital to drive sales growth and profitability.

Operator

Our next question comes from Michael Yee with Jefferies.

Unidentified Analyst

This is Dina on for Mike. I just wanted to get a sense of your assumptions for Q4 COVID jabs and what are you seeing in Q4 right now? How much of that is actually jabs and actual injections versus channel fill? And just a follow-up on that. Now that you've seen sort of half of the 2023 fall season play out, what are your assumptions for 2024 and 2025 for COVID. Are you essentially assuming that the same people who got vaccinated this year will continue to get COVID vaccine every year.

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

In terms of the fourth quarter '23 jabs, what we saw in 2022 is there is a significant portion, about 45% of the total COVID vaccination happening in November and December. This year, we're expecting a similar split, likely larger given that we launched 2 weeks later into the season in 2023 than we did last year. And what we are hearing from our different non-retail customers as well as our retail pharmacy partners, they're planning vaccination campaigns and marketing efforts to really capture on the November and December month. So in total, we do anticipate getting to at least 50 million doses this year. And we do believe that November and December will be a strong month for us. In terms of 2024, our assumption is everyone who has gotten their booster in 2023, will at least get their booster also in 2024 and beyond. Now given the higher burden of disease

with COVID, as consumers become more understanding of the annual recommendations, and as the convenience of getting both flu and COVID becomes more normalized, we do believe over time, we'll start to see some increase in the overall COVID market.

Operator

Our next question comes from Hartaj Singh with Oppenheimer.

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

I just got a question on the combination programs. And just to give a little bit of frame the question, in other therapeutic areas, aside from vaccines for infectious diseases, for example, oncology, monotherapy treatments generally tend to be a minority of treatments, 10%, 15%, 20%. Currently, monotherapy vaccines dominate the market in COVID-19 flu. So when you get the combination vaccines going, do you imagine -- does your market research tend to suggest that you would again, probably a combination approach might dominate that versus a monotherapy approach, singular vaccines going forward? And then secondly, will the cost of goods sold be any different for the combination versus the monotherapy products.

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

Thank you for the question. So we do anticipate that our combination vaccine will take a substantial share of the monotherapy vaccines that are available. We have seen in the pediatric vaccine market that upon availability of combinations, you see very strong uptake in conversion from mono to combinations, and we expect a similar trend in the adult market. From our market research, we have heard consistently from consumers that they prefer one shot over multiple shots. From a customer perspective, we are hearing as Stephane had mentioned, just with workload issues, 1 shot saves a lot of time and also helps them to get more patients protected. And from a broader health care system and government and payer perspective, we are hearing an increased need to help get greater uptake and compliance in adult vaccinations. And our health care authorities believe that combinations can help actually boost the vaccination rates. So we are very excited about our combination products in the future and think this could really be an inflection point for respiratory vaccines.

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

Yes, this is Stephane just to add to past comments. During COVID, we have been discussing a lot with health care ministers and the topic of vaccination combination has come a lot. And as you think, especially outside the U.S., where you have a lot of (inaudible) system where you have one payer, the government taking care of people from birth to death basically. We are very, very interested in combinations because they know that participants of the country got the vaccine, the production has got several viruses, which prevent hospitalization.

As you know, we've done a partnership with some countries like the U.K., Canada, and Australia and through those negotiations, the concept of combination was critical in the decision making because they see the population getting older. They were ready actually with a number of hospitalizations will just go up over time and the ability to prevent that when you see shortages of healthcare worker, and as you project those shortages in the future is a key determination of the decision. So I think we integrated healthcare system, the drive to go to combo will move even faster, but actually in commercial markets like the U.S. market.

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

Yes. And as, maybe I'll take the cost of sales question. Thank you for it. So this provides a substantial margin expansion opportunity. So if you think about our cost of sales, the smallest portion is our drug substance. So it's our actual mRNA and that's a very small portion of our overall cost of sales. Everything from drug product in terms of the cost to finish the product and the presentation type, whether it's PFS or a vial or whatever, that now gets cut in half. So when we sell to, it's a very limited amount of cost increase versus a single presentation. So it does provide a significant margin expansion opportunity.

Operator

Our next question comes from Boran Wang with Guggenheim Securities.

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

Appreciate you guys sharing early thoughts on '24 and beyond. For '24 specifically, can you talk about some of the contribution from COVID and RSV in terms of split. It sounds like you plan to get the ground running there in RSV. International, how are you thinking about the longer-term contribution from COVID as competitor premiums expire and with flu, with the comments on marking '25 wondering if you had any recent conversations with the regulators there in terms of potential approval?

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

About international sales? Thank you for the question. In terms of our expectations in 2024, we have put about $1 billion across international COVID and RSV. We do anticipate a strong launch in the second half of the year with RSV. And on the international side for COVID, we are continuing to pursue multiple options across a number of countries. In Japan, we will be in a fully commercial market is our expectation where we will be competing for the Japanese business. In the EU, we continue to work with countries on agreements to secure our COVID-19 vaccine. As publicly disclosed, the EU has renegotiated their contract with Pfizer earlier this year. So the EU demand has been substantially satisfied in many markets, but we are hearing from individual member states that they are looking for a second supplier for vaccines. And we are in those discussions right now, both at a country level, but also at a European commission level to see if a joint procurement agreement can be established in 2024.

Stephen Hoge - *Moderna, Inc. - President*

And thank you for the flu question. So as you referenced, we had really strong data out of our P303 Phase III study for flu that we released at R&D Day. We're excited about that. We are engaging right now with multiple regulators about the pathway to licensure. I don't have an update about all those conversations because they're happening as we speak. But we will, once we have clarity across all markets, on the pathway licensure to provide an update.

Operator

Thank you. Ladies and gentlemen, this does conclude the Q&A portion of today's conference. Ending the call itself. You may now disconnect, and have a wonderful day.