REFINITIV STREETEVENTS

EDITED TRANSCRIPT

MRNA.OQ - Q3 2024 Moderna Inc Earnings Call

EVENT DATE/TIME: NOVEMBER 07, 2024 / 1:00PM GMT

OVERVIEW:

Company Summary

REFINITIV

CORPORATE PARTICIPANTS

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

James Mock *Moderna inc - Chief Financial Officer*

Stephen Hoge *Moderna Inc - President*

CONFERENCE CALL PARTICIPANTS

Salveen Richter *Goldman Sachs - Analyst*

Eliana Merle *UBS - Analyst*

Gena Wang *Barclays - Analyst*

Michael Yee *Jefferies - Analyst*

Tyler Van Buren *TD Cowen - Analyst*

Terence Flynn *Morgan Stanley - Analyst*

Evan Wang *Guggenheim Securities - Analyst*

Edward Tenthoff *Piper Sandler - Analyst*

Luca Issi *RBC Capital - Analyst*

Courtney Breen *AB Bernstein - Analyst*

Emmanuel Papadakis *Deutsche Bank - Analyst*

PRESENTATION

Unidentified

(Audio in progress) Important risk factors that could cause our actual performance and results to differ materially from those expressed or implied in these forward-looking statements. I will now turn the call over to Stéphane are trued up enough.

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

Good morning or good afternoon, everyone. Thank you for joining us for ourselves. We will review of our business in the fourth quarter. Jamey will present our financial results and outlook, Stephen will review our clinical programs. I will then come back and share of key priorities before Q&A.

We did a good $1.9 billion of revenue in the third quarter. Net income was $13million barrels. We ended the quarter with cash and investments of $9.2 billion. As you know, formulary and now we have been working to improve productivity in the Company in the third quarter of 2024 compared to Q1 of 2023, we reduced operating expenses by $500 million across cost of sales, R&D and SG&A. This figure excludes $1.4 billion of resizing charge in the third quarter of 2023.

I would like to thank our teams who have been working hard to achieve these cost savings and will continue our journey to improve our cost efficiencies. This year, but probably not benefited from U.S. regulatory approval that was 19 days earlier than 2023. Spec that was available across all segments of the US healthcare system. For manufacturing and logistics teams were able to double the number of buildings and industrial customers comprehensive assessment of last year's COVID vaccine seasonal.

Now turning to US, we have seen so far this season for, but conditions in the US retail market. Progress on savings of shots in arms in the retail channels as measured by actually via, which includes retail, pharmacies and long-term care. As you can see the graphs on the left, the early approval of a vaccine this year as helped to boost total market backing those above where they were last year at this point in the season.

The graph on the right shows weekly bill is which, as you can see in the past few weeks of subleasing decline, one will not the ownership of this government to the end of the season. We are encouraged that the COVID market is starting to prove to be a sizable and durable long-term market. Moderna has 40% share of retail shots in arms season today.

Turning to Slide 7. We've been dividend food to be an acceleration in trends from last year to inform our understanding of where they are additional opportunities to grow with COVID market. There are three major delivery channels for respiratory vaccines in the US, there are retail pharmacies, integrated delivery networks or IDNs, which basically says hospitals and doctors who are part of the business works and the film group government programs and other.

As you can see the retail channel compromised 73% of total US market for COVID that (inaudible) last year in 2023, COVID vaccines have been, although it may be given to pharmacy setting research, smaller distribution in into our channel. If no cash flow in a true market how about the distribution by channel is different with much greater emphasis on IBM and governments.

Cisco project to present the much greater help rather than Flu renewing at this stage. We remain convinced that including the vaccination rate of COVID (inaudible) to provide a significant opportunity to improve, probably kept, especially in the adjacent segments and government and other secular. Therefore, as we execute our coming through energy, we see the opportunity to drive the COVID vaccination rates closer to through over time, especially in the under pressure that (inaudible).

Whereas of course, we could COVID vaccination rate over time is a combination of into the vaccine, which Stephen will discuss shortly. Let's now go to look more than I was going to go back to the asphalt to educate healthcare providers on the importance of complete as it probably kept (inaudible) if negative impact as a much greater growth of CVNS been of well exploratory analyses and the opportunity to improve public health by following bacterial contamination.

As you know, in 2023 - 2024 season, we were 3 times of prediction of COVID we've been through. Secondly, we are going direct to consumer to emphasize the benefit of getting vaccinated and our most recent campaign highlights then job long COVID and the importance of vaccination to minimize the risk province. Additionally for the type of volume is increasing, the CDC recognize the importance of vaccination, which is reflected by the most recent ACP accommodation for additional copies of these four uncompromised people and those 60 balances of those in the spring of 2025.

Moving on to RSV. More than our Q3, not unless the assets of about $10 million, this was below expectations going into 2024. Unfortunately, the timing of approval and recommendation prices (inaudible) which is telling us missing most of contracting season. Additionally, the substantial buildup of inventory in the channel by competitors prior to launch as a negative impact on ourselves.

Looking to 2025, we believe that we'll be able to participate from the beginning of the contracting season in the US was a filing for approval of a broader mRESVIA RSV label that will allow to address the 18 to 59 high-risk populations. Additionally, we see the potential for market expansion if regulators recombinant recognition. And finally, we are now starting to receive approval outside the US and we expect to have centres in those market in 2025.

I am delighted to welcome actually saying to them on the Board of Directors have us and has strong commercial background. We're expecting to have a great addition to our bulk is more than 35 years of commercial experience, most recently as CEO of Vifor Pharma and before that, Former Global President, Pharmaceuticals of GSK advances in ideal member to guide what other forwarders and continue to advance our broad portfolio of products to our commercialization in the next few years.

We very much look forward to working with us in the U.S. net. Finally, I'm very pleased to announce the expansion of more than an executive committee, expanding the responsibilities of to current members of the team and adding two new members to the team to help us ensure we execute our strategy and deliver ambitions to patients.

First, Stephen will expand his role to include the oversight of a full commercial organization, which was well-received divided into Indiana as modality that seen revenues responsible for strategy across the full lifecycle of the company, research and development and medical affairs and commercial to eliminate the executive committee our Rose Loughlin (inaudible) Rose being promoted to Executive Vice President Research.

Jackie has been promoted to Chief Medical Officer, legal developments of ammunition. The promotion of Jackie and rose to the executive committee is a special makeup of the Company. This is first time in our history that's got promoted internal talent onto the executive committee is a testament to both of those this remarkable colleague with each spent years, building LED critical areas of our company, and this reflects our commitment to grow and develop our internal talent at Moderna.

2014, our Chief Human Resource Officer, will also expand our becoming Chief People and Digital Technology Officer. The inspection, and I will emphasize the fact of the integration of before culture and digital innovation across the business has lifted the team works to scale up our business processes the ask a question of how we should do work constantly be on per night between people and digital technologies, big off-the-shelf software solutions, including our own machine learning algorithm for GPT enterprise and all robotic solution.

I would like to thank Stephen interesting for venue expanded role and how that partnership over many years, many years looking follow and to congratulate Rose and Jackie for not being part of the Company exited committee. With this, let me turn to Jamey.

James Mock - *Moderna inc - Chief Financial Officer*

Thanks for the phone, and hello, everyone. Today, I will provide an overview of our financial results for the third quarter and share our outlook for the remainder of 2024. Let's start by reviewing our commercial performance, which you can follow on slide 14.

For the third quarter of 2024, our net product sales were $1.8 billion, bringing year-to-date product sales to $2.2 million. We also had approximately $100 million in year-to-date other revenues from grants, collaboration, licensing and royalties, which are not included in the figures on this slide.

$1.2 billion of our 3Q 2020 for product sales from the US market, where we experienced an earlier launch to the 2024-2025. While our 3Q results exceeded expectations is mainly due to sales timing between the third and fourth quarter, supported by receiving FDA approval of our updated COVID-19 vaccine three weeks earlier than last year. Also included in our US sales of $1.2 billion is a provision release of approximately $140 million, primarily driven by lower product returns from the 2023-2024 season compared to our previous estimate.

Additionally, we commenced RSV vaccine sales in Q3, while in the (inaudible) sales were limited at $10 million, we believe there is potential for long-term growth as we work to capture a larger market share over time. International sales of $0.6 billion were in line with our expectations for lower compared to the same period in 2023. When sales benefited from the fulfilment of quarters deferred from 2022.

For full year 2024 outlook, we are reaffirming our product sales adjustment of $3 billion to $3.5 billion, which implies a 4Q product sales range of $0.8 billion to 1.3 billion. We expect our US 4Q product sales to be between $200 million and $500 million

The range is driven by the following three key variables are slightly our market share, which is currently tracking to approximately 40% in retail. At this time, it's too early to call a share in and year end and with the governments. Next vaccination rates arrangements in the market size, which as COVID vaccinations flat to down 10% versus the prior year. Finally, our performance in and the ultimate size of the RSV market in 2024.

To summarize, yes, our retail market share remained constant at 40% and the US market finishes the season down 10% compared to last year. And there is no uptick in RSV sales. We expect to be on the low end of the sales range. We expect our international Ford's new product sales to be between $600 million and $800 million. We have a tighter range on our international sales as most of these sales are for contracted volumes and confirmed orders. The final international sales amount will be dependent upon revenue recognition, timing and our performance in a few specific markets.

Moving to slide 15, I will talk about our 3Q financial resulted in more details. Net product sales for Q3 were $1.8 billion as I just discussed on the prior page. Our cost of sales for 3Q 2024 was $514 million representing 28% of net product sales for the quarter. This was 77% year over year decline in our cost of sales from $2.2 billion in Q3 2023.

As a reminder, last year, we undertook a strategic initiative to restructure our manufacturing footprint and recorded $1.4 billion of charges in 3Q 2023. From inventory write-downs, CMO wind-down costs and cancellation fees. Excluding the $1.4 billion charge, cost of sales still deploy and by 13% year over year as we continue to make progress driving additional productivity improvements in our manufacturing operations.

R&D expenses were $1.1 billion in Q3 2024, reflecting a 2% year over year decline from $1.2 billion last year. We purchased a priority review voucher during the third quarter of 2024, which is included in our Q3 results. Excluding the PRV purchase, we had a strong year over year spending declines for research development and clinical manufacturing as we continue to drive cost efficiencies across all areas of the organization.

SG&A expenses for Q3 2024 were $281 million, representing a 36% year over year reduction. This decline reflects our focus on driving cost efficiency and making targeted investments that continue to strengthen our overall productivity. I will provide further details in the following slides.

We recognized an income tax of $8 million for the third quarter, a significant reduction from the $1.7 billion in the same period last year. The decrease was largely attributable to the establishment of a $1.7 billion valuation allowance on deferred tax assets in Q3 2023. The valuation allowance has remained inflations, its initial recognition and continues to impact our tax expense. Our net income for the period was $13 million, a notable improvement from the net loss of $3.6 billion recorded in Q3 2023.

Earnings per share for the quarter was (inaudible) $0.03 compared to a loss of $9.53 per share in the same period last year. We ended the quarter with cash and investments totalling $9.2 billion, down from $10.8 billion at the end of Q2. Primarily due to ongoing research and development expenses and operating activities.

Moving to slide 16, I want to provide additional details on the cost reductions we are driving across the Company. As discussed on previous calls, as a platform company, we are building a unique operating model and over the last few years, we have invested purposefully into people, processes and technologies to build foundational capabilities that will allow us to scale efficiently.

We continue to see these efficiency gains in our 2024 results. As mentioned on the previous slide, we reduced 3Q SG&A expenses, but by 36% year over year, we had year-over-year reductions across all areas of our SG&A categories, commercial, medical and SG&A, functional (inaudible). There major drivers were from reduction in purchase services and external consultants as we better leverage digital technology and AI.

Year-to-date, our SG&A spending is down 24% year over year. While we continue to drive productivity improvements, we are also committed to increasing COVID-19 vaccination rates with investment in HCP education and consumer and ad campaigns as well as increasing our COVID-19 and RSV market share in competitive markets.

Therefore, we don't expect as large a year over year decline in 4Q SG&A spending versus the prior year. For the full year, we expect SG&A to be down approximately 20% to $1.2 billion, which is reflected in our financial framework update on the next slide, turning to that 2024 financial framework on Slide 17.

Our net product sales guidance remains at $3 billion to $3.5 billion as reviewed earlier, there are a handful of factors we are monitoring as the season progresses. For cost of sales. We are narrowing our guidance at 40% to 45% of product sales as a result of the continued manufacturing productivity improvements we are driving in the Company. For R&D. We are lowering our full-year estimate of $4.6 million to $4.7 million from our previous guidance of $4.8 billion.

The reduction is due to cost savings from productivity improvements as well as clinical study timing. For SG&A, we continue to expect full-year expenses to be approximately $1.2 billion, down from $1.5 billion in 2023, a decrease of approximately 20% year over year. We continue to expect taxes to be negligible in 2024, and we are updating our capital expenditures outlook to approximately $1.2 billion, which reflects the purchase of our Norwood campus from our landlord for approximately $400 million, partially offset by approximately $100 million of other CapEx reductions.

The purchase of this highly strategic asset allows us full control to expand and build out the campus to drive future productivity and innovation. We anticipate this transaction will close in December. We can continue to expect ending 2024 was approximately $9 billion of cash and investments. The additional cash outlay for purchasing our Norwood campus will be offset by reductions in our cost of sales, R&D and other capital expenditures. Based on our 3Q actual product sales $1.8 billion. We have strong visibility into our expected cash collection timing from our customers in 4Q. With that, I will now hand the call over to Stephen.

Stephen Hoge - *Moderna Inc - President*

Thank you, Jamey, and good morning or good afternoon, everyone. Today, I'll do a quick review of our pipelines and R&D event in September, we discussed our focus on 10 product approvals over the next three years. Today, I'll briefly summarize the status of those programs. Starting with our respiratory vaccine portfolio for our next generation COVID vaccine mRNA-1283, we are pleased with the positive phase three safety, immunogenicity and vaccine efficacy data we presented in R&D debt.

Including a 13.5% higher vaccine efficacy compared despite thanks in participants aged 65 and older in that study. As previously shared, we intend to file mRNA-1283 to probably three for approval in 2024 and will use a priority review voucher.

For our RSV vaccine, mRNA-1345, and we also shared positive safety and immunogenicity data from our Phase 3 trial in participants, 18 to 59 years old, who are high risk from our IC. We are also using a priority review voucher for this program, which we intend to submit this year.

We also shared positive Phase 3cdata from our combination through COVID vaccine, mRNA-1083 and intend to file for approval in 2024 subject to ongoing discussions with FDA. We have decided not to use a priority review voucher for this program given the timing of submission and the potential launch relative to the respiratory viruses in 2025.

We will announce could do for dates for these programs if and when they are confirmed by the FDA. Moving now to our standalone flu program, mRNA-1010, we have initiated in substantially enrolled the first season of our Phase three vaccine efficacy study. As a reminder, this Phase 3 study is funded within our project financing agreements with Blackstone Life Sciences.

Slide 20 shows the study design for that Phase 3 standalone include flu vaccine this is a randomized observer, blind active control study mRNA-1010 against standard (inaudible), it is designed to be enrolled over two seasons for the study has the possibility to declare early success after a single season.

Now turning to our non-respiratory portfolio, starting with our Leighton and other buyers exits for our CMV vaccine, we continue to expect that we will improve the 81 cases required for the interim analysis in our Phase 3 study by the end of this year. Following the accrual of these cases, the Data Safety Monitoring Board, we will conduct a statistical analysis, should they recommend unblinding at the interim analysis, we will share those results.

For norovirus I'm happy to announce that we are rapidly enrolling our Phase 3 trial in a moment I will take you through the study design of that norovirus Phase 3 study. In oncology, we and our partner, Merck, have initiated a Phase 3 trial evaluating edge of (inaudible) mRNA-4157 in combination with KEYTRUDA after neoadjuvant, KEYTRUDA and chemotherapy in patients with certain types of percentage non-small cell lung cancer.

This is the second Phase 3 trial for INT in non-small cell lung cancer and is targeting patients who may not respond to new adjuvant therapy alone. I'll also review this study certain design in the upcoming slides. For our rare disease therapeutics, we intend to begin to generate pivotal trial data for our PA program in 2024 and for M&A, we have an agreement with FDA on our pivotal trial design we now expect to start that study in the first half of 2025.

On Slide 22 is the design of our Phase 3 study for our norovirus vaccine candidate. As a reminder, norovirus is a gastrointestinal disease with high unmet need and no approved vaccines on the market. The Phase 3 study design test, the efficacy, safety and immunogenicity of our vaccine in 25,000 adults aged 18 and older. Randomized one to one observer blind and placebo control.

Turning now to the trial design for our second Phase 3 study in non-small cell lung cancer for INT in collaboration with Merck, which complements the Phase 3 interim past (inaudible) to trial this Phase 3 study called interim past (inaudible) we will enrol more than 1,200 patients with Stage two to three the non-small cell lung cancer without an EGFR mutation and who are able to undergo surgery.

These patients will receive neoadjuvant therapy for Keytruda plus chemotherapy, followed by surgery following surgery the study will randomize approximately 680 patients who have not achieved a pathologic complete response in the two arms combination of INT plus KEYTRUDA or KEYTRUDA plus placebo. The primary endpoint for this study is disease free survival and secondary endpoints include distant metastasis, free survival and overall survival. With that, I will now turn the call back over to Stéphane.

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

Thank you, Stephen and Jamey. During R&D Day in September, we feel the Company priorities, priority one to drive sales of approved products, Starbucks in Namibia property two focus on our late-stage pipeline, where we believe we can have up to 10 product approvals over the next four years so we should be drivers of sales growth. Priority three to deliver cost efficiencies across the business and slower pace of all the investments, reducing annualized expenses by $1.1 billion, something equivalent 27.

Of course, properties in rough terms of buybacks and M&A. Yes, which we believe the foundation of our respiratory vaccine portfolio. We will continue to work with all market channels to maximize production availability. We are focusing on marketing and medical education to trying to drive with COVID vaccination rate goes up a vessel through over time. Internationally we're glad to Greek manufacturing plants online in the UK in Canada and Australia in 2025 mRESVIA for accretive multi-year contract in those countries. And we foresee them advisory contracting in the U.S and I look at for the 2025, we expect to increase Elementia segment market share.

We are focused on a range of 5 to 10 product approvals over the next three years, which we will improve our sales growth and size of the next wave of 5G business. For eight of these programs, we have near-term milestones for CMV we expect with rigor of the interim analysis for Phase 3 efficacy study by the end of this year.

We're looking at for what those results for PNM I mean, we plan to initiate pivotal studies on nobody else and through pretty scary vaccine efficacy studies are now underway. Finally, we schedule five as we progress into (inaudible) an exit COVID vaccine for RSV vaccine for high-risk 18 with net yields and load competition Covid productivity subject to ongoing discussion with the U.S. FDA.

We will continue to focus on improving efficiency by the federal R&D and SG&A expenses flat to down in 2025. And as demonstrated in the quarter, we're making progress on our cost saving initiatives already by 2027, we expect to decrease and your R&D expenses by $1.1 billion on the cost of sales will continue to drive efficiency, and we expect to achieve more proactive in the acreage that we were flagging aframework we showed previously.

We have some products improved, definitely protect people every day. We have a long business pipeline for medium and the Company and will continue to focus on data of aggressiveness, placebo impact to portfolio management suite, where we work to be done to meet our existing ships. (inaudible) and Continental team will be able to achieve our goals and cause it to be excited about the potential we have to deliver for patients. The actions we are we are taking 200 people is becoming a reality. With these operators that would be happy to take questions.

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator instruction) My first question comes from Salveen Richter with Goldman Sachs. Your line is open.

Salveen Richter - *Goldman Sachs - Analyst*

Thanks, and good morning. And two questions for me. One is can you speak to the source of the rest of world revenue generated in the third quarter and expected in Q4 with regard to which continues our constituting hands on them, these contracts that you should you expect them to recur in 2025? And then separately on CMV and moving on, you talked about both the DSMB your share, the results of the DSMB recommended unblinding. Can you speak more to them as to whether we will actually get interim data provided to us or we're going to have to wait for the full analysis? Thank you.

James Mock - *Moderna inc - Chief Financial Officer*

Sure. Thanks for that question, Salveen. I'll take the first one in terms of rest of world revenues. So, without getting into too many specifics, I think you know, we're establishing a presence in the United Kingdom in Calgary, Canada and Australia we announced an order in Brazil and so that's been the balance will be shipped either in the third quarter in the fourth quarter.

And when we look at the fourth quarter of the $600 million on the low end of the large majority of that is contracted with those countries and others but I just wanted to name a few. As we look to 2025, I think as we mentioned at R&D Day, that there will be a decline in some of those countries and then it will then uptick or anticipate 2026 on the contracts that we have in certain countries.

So that is available on the rest of world split. And on the CMV question down to that, if the DSMB recommended unblinding to sponsor at the first interim analysis to your question, that would be because we met the criteria for vaccine efficacy and obviously we would share those results around if we receive them, there is a chance that the DSMB will not recommend unwinding and which would mean perhaps that we did not meet statistical significance in that first interim analysis and the going then to the final analysis, which could happen quite quickly and depending upon the conditions with that communications and the timing of that final analysis, we may or may not be communicating Ray-Ban about that we are waiting for that final analysis. But we would in any event if the DSMB recommended unblinding share business results.

Operator

Thank you. Our next question comes from Elliana Merle with UBS. Your line is open.

Eliana Merle - *UBS - Analyst*

Thanks for taking the question. And just another one on how to think about our (inaudible) covenant revenues on. In the past, you've talked about some contracts with some countries for guaranteed pension funds like come in and drop under the (inaudible). Maybe can you just in broad channel to characterize this Pfizer's from (inaudible), our contracts that you have outstanding (inaudible) from the Thailand floods essentially guaranteed from a revenue perspective here arm in terms of some ideas of (inaudible)contracts? Or has it will have a sense of maybe like what the minimum (inaudible) of excellence can be arm? And secondly, there's time to time based on that. And then just a second follow-up on CMV. I think you alluded to this in the last answer, but maybe just in terms of the like the of accruals, I guess what's your latest expectation in terms of timeframe between when you are accruing a number of events to trigger the interim versus the number of events to trigger the final analysis? The timing between as those two. Okay.

James Mock - *Moderna inc - Chief Financial Officer*

Yes, sure. So, I'll take the first (inaudible). So in terms of the contracts that we have, it with some of these countries are not going to disclose the specifics. But what I will say is that as we add products over time, you can imagine that the amount of the minimum purchase commitment will grow over time. So that's why, as I just mentioned in my prior response, that it will drop in 2025 and then start to grow in 2026.

Stephen Hoge - *Moderna Inc - President*

But I don't think we're going to disclose anything more than that. Some of the question on CMV and the timing of kit to grow, and it is coming quite steadily in right now. And in fact, we do have a bit of a backlog of case confirmation that we are working through them. There's multiple steps that have to go with multiple testing to validate the case. And so we actually I obviously don't control the rate of case accrual on, but we do expect operative. And if we are doing that final analysis, that it won't be a very long period of time between actually could happen quite quickly.

Eliana Merle - *UBS - Analyst*

Okay, thanks.

Operator

Next question comes from Gena Wang with Barclays. Your line is open.

Gena Wang - *Barclays - Analyst*

Thank you. I have two questions. one is regarding the commercial questions. If we calculate $1.2 billion U.S. revenue and accumulate $19 million U.S. doses is the cancellation like $63 per dose as a net price in the right way to think about it? And then regarding the reserve return, could you provide a final we just returned from last winter season and what is your reserve return so far for this winter season? And I quickly regarding a flu combo, a flu (inaudible) and not using power value chain and maybe give us a little bit more rationale for this. And I will also be that you submitted here. How many of these will make for 2025 winter season?

James Mock - *Moderna inc - Chief Financial Officer*

Yes. Maybe I'll take the first question. So on the US pricing, the $19 million, I think, is the total market you might be referring to and for COVID vaccinations, not specific to the data. That said that the pricing that you're talking about, we won't specifically this close, but it's not that far off

---

Stephen Hoge - *Moderna Inc - President*

Come on the pipeline question to you and thank you for both on. So first on the priority review voucher for the flu COVID combo, given where we are in terms of timing of this year and relative timing of the contracting season for flu vaccines. And we no longer think it makes sense to use a priority review voucher dry and accelerate that process for. But ultimately, we believe we would miss the contracting season for that region will hold back that PRB and use it for different products in the future.

And as far as the submissions and as we confirm today, we are expecting to the other two submissions to go forward with priority review vouchers and given the timelines on, you can understand that we think that means approval next year, is it possible and can happen prior to the season. However, now we do not include any revenue from either the 18 to 59 RSV (inaudible). or mRNA-1283 in our 2025 guidance or expectations. And so, if we were able to deliver those with appropriate view centre rub, we still wouldn't include any revenue that would be an upside.

Sorry can you repeat the question? Gena, if I missed this in our sales return part.

Gena Wang - *Barclays - Analyst*

Reserve return is, could you provide a final reserve return from last winter season? Because I know you initially booked five over $500 million into adjustment to see the final numbers. So if you could provide the final numbers and what is your reserve risk return assumption so far for this when incision?

James Mock - *Moderna inc - Chief Financial Officer*

Yes. So Lam to, as I mentioned in my prepared remarks that we released in the quarter about $140 million, primarily driven from a return's reserves being lower than our prior estimate, stood at $500 million plus went down to, let's say, $400 million for the prior season. So we learned from that and continue to forecast what an anticipated products with returns reserve is for this season, and we will continue to monitor it as we look at vaccination rates throughout the entire quarter and what we projected into the first quarter of next year.

Operator

Our next question comes from Michael Yee with Jefferies. Your line is open.

Michael Yee - *Jefferies - Analyst*

Thank you. Two questions not 10, but on the combo, I know that you say you're in discussions with the FDA can you just clarify what are the different factors that are contributing to why you have lack of confidence on filing or I guess not certainty on filing the combo, for example, would there be an infection today that to be run a little unclear to us on the combo?

And then on RSV I think the market anticipated dishwash can be a big market. However, RSV there are a lot in fact dynamics going on there. And maybe comment on whether you think there will be a change to this market and what we gave you confidence that you're going to actually be a player here, given you've already given, I guess, given your competition now and where your guidance is for 2025? Thank you.

Stephen Hoge - *Moderna Inc - President*

Thank you for both questions come. So first on the I'll take the combo and Mr. Stephane on the RSV. So first, we are in discussions with the (inaudible) data for 1083, as you remember, teams or middle of this year and so we've only more recently had the opportunity to be sharing that and engaged in discussions about what would be in the BLA for accelerated approval of candy three based on the immunogenicity results.

I would not comment on those discussions back and forth we continue to work closely with the agency to understand what they would like to see in that we continue to believe, as we said today, that we will be submitting for approval this year. Although those conversations are ongoing, and we'll update as they proceed forward.

The decision not to use the priority review voucher, which became wondering about the timing of that approval. And ultimately, our view that from that would that we would miss the contracting season for influenza and therefore didn't make sense to do that but by withdrawing priority review voucher, we also allow for a more for some time for review, which is also obviously the benefit of ourselves and the agency.

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

On the RSV, Mike, I think there's a few things. As you know, the market has been much lower than last year and much more willing to participate in are obviously the new CDC guidelines that came out in the June timeframe impacted that you have a piece we are hearing from customers. You have that refocus on making sure people get COVID it through vaccination right now.

So these would be quite interesting to see what happens in Q1 potentially and thus, the shape of the curve of (inaudible) different than what we saw in the produce season so that's to be see. The other piece is because through contracting and because of what happened last year and as new contracting happened before the CDC guidelines, there's quite some of our volume in the channel, whether book by the retailers themselves and in (inaudible) and so of course, we've had much lower market and there's a lot of inventory in the customers had both was seller and we can from (inaudible) vaccine is taking quite some time to go through that the inventory.

And so we think that there's an interesting question about the market dynamics in terms of timing. Again, with Q1 being more important climbing (inaudible) into question to be seen. Of course, we expect U.S. mall-based accumulate. CTC will cause you to review and look at what's the right guidelines with us forever for because we do have to decide and being a bit of a burden to the new contract COVID NIC at the same time for foresee them, we believe is going to have an impact in the US and you have a piece of Mexico's remodelling off these outside the US, which does you know, we are not held outside the US. We are getting approvals and Nagano to continue to happen in the months to come. So we believe 2025 and beyond should also help us five years.

Michael Yee - *Jefferies - Analyst*

Thank you.

Operator

Our next question comes from Tyler Van Buren with TD Cowen. Your line is open.

Tyler Van Buren - *TD Cowen - Analyst*

Hey, guys, good morning. Thanks very much for taking the questions. So I wanted to ask about US COVID vaccine sales. So that were roughly flat quarter over quarter between Q3 and Q4 last year with the vaccine until guidance for Q4 this year assumes a decline as much as 60% to 80% quarter over quarter of our US results remain low and my math is correct? So is there a significant shift occurring this year to vaccines being available earlier, patients getting vaccinated earlier that you expect to be the dynamic moving forward? Or could this guidance be conservative? I just ask because it's pretty dramatic change in the cadence of U.S. sales so any additional color would be appreciated. Thank you.

Stephen Hoge - *Moderna Inc - President*

So if you think about the US market, I think what is important for us is to look at the different channels because we are very few fronts. As we've shared the data that we have is the efficacy data for retail, long-term care facilities, as you see yourself to that to date a little bit ahead. But if you look at the weekly scripts, we are coming down the peak we hear from and we said it was about walking real in some of them vaccination campaign ahead of and giving. It gives us plan ahead of Christmas between Thanksgiving and Christmas. But that is to be seen what happens with the leadership of Pepco. And then there is the IDN networks. As I said in my remarks, we have been working really very deep networks to increase the COVID flu vaccination rate versus last year.

We built up a lot of visibility because those campaign started later most of them early October. We assume the retailers starting in August, which saw them something for very strong in August and early September and that the government data for which we have no visibility, we only get all those women are those coming. So it's still I mean, this season, the shape is clearly different from last year and we carry we are hoping that we will work over returnable, and I'll walk you might pay it off with your friendship and last year and then IDNs and government. So we'll have to see, and we believe cause you to know them, but this market, but we believe it still remains stable and (inaudible) direct, what we see that in many millions of people who want to a COVID vaccination.

James Mock - *Moderna inc - Chief Financial Officer*

Yes. Maybe I'll just add that remember, when we sell product, that is that tied to vaccinations. So, when you look at the decline from the third quarter to the fourth quarter, we had an early approval, just a final point to, therefore, can we were better ready to ship more within the third quarter. So that what I think you see on a year-over-year basis, what's happening?

Operator

Thank you. Our next question comes from Terence Flynn with Morgan Stanley. Your line is open.

Terence Flynn - *Morgan Stanley - Analyst*

Hi, thanks for taking the question. I was just wondering on the INT program obviously are continuing to accelerate the clinical program here with the new Phase 3 among. But can you just give us an update on the manufacturing facility in Massachusetts and if that's still on track for completion by year end? And then if there's going to be a bridging work required by law, FDA for approval or validation. Thank you.

Stephen Hoge - *Moderna Inc - President*

Good morning, Terence. Yes, over the (inaudible) do a great job or in the plant revolver, progress up the value on schedule and so given what we showed at (inaudible) and some of your timing we have here, the plants are will no longer be critical path to approval. But we're keeping the team working really hard and they are making great progress, were very pleased with that. And on the question of bridging come, once the plant is operational, will transition our clinical work to that plant as well and so effectively, all the programs will include some from many of the programs may include, I should say on that data to the bridging will be done instream.

Operator

Thank you. Our next question comes from Evan Wang with Guggenheim Securities. Your line is open.

Evan Wang - *Guggenheim Securities - Analyst*

Hey, guys, thanks. And two from me. First on the election results just wondering, given the pending change in administration, what Gary Burge in place from policy or legislative standpoint that would meaningfully women's rights to companies that in the US, what steps are you doing to reach and are confident try and protect against potential increase in legal liabilities? And one RSV of some competitors are describing how data announced dividend for expansion in international revenues at you agree there and what gives you confidence in Fairness Act you have specifically? Thanks.

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

Good morning. Your final question. As you know, our mission of the company is to bring innovative medicines into well people, our prevent disease, (inaudible) disease since the company funding with work very closely with governments, media and public, a few deals around the world, including, of course, the U.S. And as you know, we work very collaboratively we've further for exerts drug-drug his first term and so we're going to continue to do that.

Our mission is to leisure we help people, or do we increase of 3%, which is to then you're like me what the administration is then work on RSV outside the US, as you know, the markets have approved, the products are very different times outside the U.S. We are very similar process that you have in the U.S. once you get approval to get for fall recommendation with (inaudible) quality, which in some markets up and at different times, then you have pricing negotiation, which, as you know, are quite different outside the U.S, in the U.S. some timing might be, if you will see that because the timing of those different elements, as you know, in the U.S. is of no pricing negotiation where you can lose some time most of cross-sell.

So I think the so our ramp outside the U.S., who is reflecting both the recommendations that sometimes tend to be fall for the population, about 70 of avoid some countries, 75 and the goal and just the timing of orders in the case of mechanics to come together and then you get your quick you've done by a few weeks and you're just me as the season. So those are the dynamics happening outside the U.S. would cause you to believe

that by the causes of utilization and helps people will argue vaccines level, the meaningful steps to prevent people are difficult to utilize, especially if you think in some of a tailwind. But we have an aging population in Europe, we have an aging population in Asia.

And so I continue to believe that the overtime BIC markets outside the US would be an important market that has a lot of education to move up. The consumer level of consumer doesn't even know what our view was until recently. So I don't know as of today, seven some doctors so this is a lot of work to do. But the devices nothing before surveys a need there. And we collectively need to work with probably country bills to prevent hospitalization.

Everybody knows, especially in government that Siegel payoffs that vaccines are most probably the best all I got that you get it done, what has kept all and the best way to know hospitals with too many products to get production.

Operator

Thank you. Our next question comes from Edward Tenthoff with Piper. Certainly, your line is open.

Edward Tenthoff - *Piper Sandler - Analyst*

Thank you very much. Appreciate all the time and all the detail just looking at the orphan disease pipeline on with respect to our pivotal trial starts for MMA in first half, and I think also maybe touch on generating some registrational of this year. What do you see is sort of the path forward here in terms of either the trial design, patient numbers follow up on? When do you think we could actually see on these two data that could lead to the home filing here? And thank you.

Stephen Hoge - *Moderna Inc - President*

So that in both-cases and be moving forward, as we said, either permanently or very quickly in 2025 in the case of M&A in a pivotal study design. And the answer is a little bit different for both in the cases and it may, as we've discussed previously. And we do believe there is a biomarker that can serve as the basis for approval. That's the subject of our discussions with the FDA that biomarker resolve that you can imagine can be achieved somewhat more quickly. Then in the case of PA we will be looking at because there's not as clear biomarker will be looking at event rates, which currently take some more time come in any event.

And it will depend upon the rate of enrolment in those studies and then how quickly we can get to the deal. Ultimately, we hope is that a significant benefit of either with the biomarker or with the event rates compare as we've previously described at the R&D day. And we do expect that can happen within the next couple of years come and our goal is to be launching that product in that sort of third window 2026 plus but both of those cross, I should say, three to six plus time horizon. If we accrue patients more quickly into those studies, it could be sooner if it takes longer to be a little bit longer and we'll obviously update as we go forward in how we're doing in enrolment in those studies.

Operator

Our next question comes from Luca Issi with RBC Capital. Your line is open.

Luca Issi - *RBC Capital - Analyst*

Thanks so much for taking my question. Maybe on our sees us with this year has been more challenging, has been in the late approval versus a time that it's contracting season. But how should we think about next year? Do you think it is fair for us to assume isn't yet a third of the market share given prefilled syringes and obviously no GBS? Or do you know there will be optimistic? And then maybe second on COVID in the US on how should we think about again, about market share here are listed in the law last year, you were gaining some share versus Pfizer versus this year. Looks like you're maybe losing some shares versus them. So wondering if you can offer any additional colour on that. Thanks so much.

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

Sure. So on that as we I mean, across products, we don't guide on shelf. So we're not going to stop guiding or share. As I said, we believe very much all that being able to be contracting for season, I will be quite different from last year. So we've played itself in the 2025 season. In terms of COVID, you're correct in some of the return of market we have lost some market share as we've indicated earlier in the year. This has been quite an intense competitive environment in the US. What we don't know yet is the share in repair facility in the IDN and go unless we get a sense of both the share holistically at the end of this season so that's a bit where we are onstage.

Luca Issi - *RBC Capital - Analyst*

Thanks so much.

Operator

Our next question comes from Courtney Breen with Bernstein. Your line is open.

Courtney Breen - *AB Bernstein - Analyst*

Financing. Thanks for the time today and appreciate getting a question in a sense on that I was asked was around the INT on obviously you have just initiated this new (inaudible) trial in non-small cell lung cancer, and that has the chemo combo are proceeding in the INT. And does it change at reasons as to why you might be doing at running the trial that way could be that you're seeing tightness on the current paradigm is a falling in the direction of chemo combination has scientific to the belief that INT works well in the post-chemo space, all kind of just about practical training trials in preparation. Can you give some context to that particular trial design? And then as we think about expansion of this program more broadly into other tumor area and kind of what's primarily gating now, is that the scientific signal there is that manufacturing capacity for the maintenance downtime?

Stephen Hoge - *Moderna Inc - President*

Great. Thank you for both questions. Some to first, in non-small cell lung cancer context, there has been a move is really evolving standard of care, just driven towards neoadjuvant use of Shire checkpoints and Keytruda specifically. And there are a number of patients is that have a pathologic complete response clearance of their tumour data elements of that as a result of that, Neil Agilent chemo plus has gone KEYTRUDA.

And so recognizing that there's a move towards that standard of care, we also want to confirm the potential for INT to benefit those patients. Obviously, you wouldn't be expecting a substantial benefit on those that have had a pathologic complete response because fortunately, they do have very good clearance or two tumour. And so the structure of the study is to oversee enrol patients, allow them to get that treatment and approximately half, you can see that (inaudible), we would expect to not have had that pathologic complete response, and that's the group and then we then randomize and go see whether INT can add on top of Agilent at that point, KEYTRUDA treatment with further KEYTRUDA, some.

And I really think the driver there is a view of where we see potential standard of care moving in the lung cancer space towards neoantigen and usage of KEYTRUDA. We there may be other applications you're thinking more broadly where neoadjuvant treatment starts to emerge and we choose to go study the benefit of INT in the neoadjuvant setting not just in the adjuvant side.

As far as other indications on the short version are that we continue with our partner, Merck to systematically look at all the places that we think that I actually can offer a benefit we aren't done ye there are more studys coming and we are pacing ourselves as we stand up those investments. But manufacturing capacity is only one of the considerations it's not the primary consideration to some extent. This is about also just pacing the start of the studies.

As you can see, we're starting to build quite a large Phase 2 and Phase 3 program, and we just wanted to be disciplined about not having to meeting at the same time. So we will continue. We do continue to discuss with our partner, Merck, additional Phase 3 programs we will start new ones in the coming year that we haven't yet announced but and but we will see ourselves both for manufacturing and just simply the ability to execute in the overall scale of that of that program.

Operator

Thank you. Our last question comes from Emmanuel Papadakis with Deutsche Bank. Your line is open. Please go ahead and roll out about. T

Emmanuel Papadakis - *Deutsche Bank - Analyst*

Thank you for a quick question on the Emmanuel Papadakis from merchandise on behalf of the mine mill. So if approved, how quickly do you expect the new market transition to combination can call them, and we would expect to happen in 2025 already or more above our midterm a phone call? And secondly, what's the latest update it in perspective to have owned the COVID mitigation particular and just gains recent lawsuit? Thank you.

Stephen Hoge - *Moderna Inc - President*

Okay. Our positive outlook. I'll take the first question on timing and so on flu COVID, some obviously, it depends upon approval and it's also dependent upon on public health through recommendation from a purely commercial launch timing perspective and contracting perspective. We do not believe that 2025 is the timing of that will happen this because a majority in the United States, the majority of the flu contract (inaudible) happening really is currently in the year in the first quarter of the first half. And for that reason, given the timing of our current submission and approval, we wouldn't expect that to be 2025 that we would hope that it would happen in 2026. And ultimately, we are working towards that because we see a huge potential public health benefits in terms of prevention of hundreds of thousands of hospitalizations in the United States.

If we can improve compliance with a COVID vaccine, things as well as deliver highly effective flu vaccine, um, but again, the timing of that will be contingent upon regulatory review process and then often that recommendation processes in different markets. Over the long term we are believers that from a combination flu, COVID product in the right way for us to be protecting those at high risk of respiratory viruses seasonally in the markets in which we play and so from a very long-term view, and we are quite bullish on the opportunity of the combo price.

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

So we will not comment on the merits of GSK's case. We would note that such lawsuits are not uncommon during market formation of new technology, and we are prepared to defend also from these games we look forward to presenting our case from one scheduled.

Operator

Thank you. Ladies and gentlemen, this does conclude the Q&A portion of today's conference. I would like to turn the call back over to Stephane for any closing remarks.

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

Thank you, everybody, for joining us today. We look forward to talking to many of you in the next days and weeks. Have a great day.

Operator

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