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MRNA.OQ - Q1 2025 Moderna Inc Earnings Call

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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Good day and thank you for standing by. Welcome to the Moderna first-quarter 2025 conference call. (Operator Instructions) Please be advised, today's conference is being recorded.

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

Lavina Talukdar - *Moderna Inc - Senior Vice President & Head of Investor Relations*

Thank you, Kevin. Good morning, everyone, and thank you for joining us on today's call to discuss Moderna's first-quarter 2025 financial results and business updates. You can access the press release issued this morning as well as the slides that we will be reviewing by going to the Investors section of our website. On today's call are Stephane Bancel, our Chief Executive Officer; Stephen Hoge, our President; and Jamey Mock, our Chief Financial Officer.

Before we begin, please note that this conference call will include forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Please see slide 2 of the accompanying presentation and our SEC filings for important risk factors that could cause our actual performance and results to differ materially from those expressed or implied in these forward-looking statements.

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

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

Thank you, Lavina. Good morning or good afternoon, everyone. Thank you for joining us today. I will start with a review of our business in Q1. Jimmy will present our financial results and our outlook. Stephen will review our clinical programs, and I will come back to some key priorities and catalysts before we take your questions.

Let me start with a review of our financials. Our Q1 revenues were $0.1 billion, had a loss of $1 billion. These were in line with our expectations and reflect the highly seasonal nature of our respiratory vaccine business. We ended the quarter with $8.4 billion in cash and investments.

As you are aware, we are focused on financial discipline. I'm pleased to announce that continued cost reduction efforts in the first quarter of 2025 led to a 19% reduction of cost of sales, R&D, SG&A combined compared to the first quarter of 2024. I would like to thank our team for the great work.

During the quarter, we made solid progress against our three priorities: priority number one, expanded markets for commercial products. Earlier this year, we were awarded a tender opportunity, allowing us to complete for COVID vaccine business in Europe. Additionally, during the quarter, mRESVIA received approvals in Australia, in Taiwan and in the UK and most recently, in Switzerland. This is in addition to a program we received in 2024 in the US, EU, and Canada.

Our second priority has a single pipeline to drive sales growth and diversification. I am excited to announce the expansion of our oncology portfolio with Checkpoint medicine, which Stephen will review later. For Phase 3 flu program, we have exceeded the required number of case accruals to run an interim vaccine efficacy analysis. We also projected encouraging data from our key programs, including RSV, CMV, and IAC at reset medical conferences.

We are pleased to share that IC will now be known by the high end of international nonproprietary name of intismeran autogene. This is in addition reflects the growing maturity of our product development program and make an important milestone as we continue adapting towards potential regulatory approvals.

And finally, on our third priority, executing with financial discipline. The first quarter of 2025 marks the third consecutive quarter we will reduce combined R&D and SG&A expenses by double digits year-over-year.

With that, let me turn to Jamey.

James Mock - *Moderna Inc - Chief Financial Officer*

Thanks, Stephane, and welcome, everyone. Today, I'll cover our first-quarter financial results, our full-year outlook, and an updated operating cost framework as we look ahead to 2026 and 2027. Let's start with our first quarter financial results shown on slide 7.

Net product sales were $86 million, driven primarily by COVID vaccine sales. The US accounted for about one-third of total sales with the remainder from international markets. This result was in line with expectations given the seasonal nature of respiratory vaccines with most sales anticipated in the second half of the year.

We observed lower vaccination rates compared to Q1 last year, reflecting the continued transition of COVID into routine seasonal vaccination patterns. In addition to product sales, we recorded $22 million of other revenue, bringing total revenue for the quarter to $108 million, a decrease of 35% year-over-year, but in line with expectations. Cost of sales for the quarter was $90 million compared to the first quarter of 2024, cost of sales decreased $6 million, primarily due to lower sales volume.

While total sales declined year-over-year, it represented 104% of net product sales this quarter, up from 58% in the prior year, driven by lower volume and revenue mix. R&D expenses were $856 million, a 19% decrease year-over-year. The decline was mainly driven by lower clinical development spend across our respiratory programs reflecting the timing of trial activity and the wind down of certain studies.

This was partially offset by continued investment in our norovirus program and oncology. SG&A expenses were $212 million, down 23% year-over-year. The decrease was driven by broad-based cost reductions. These reductions reflect our continued focus on streamlining operations and managing costs across the organization.

We recognized an income tax provision of $7 million in the first quarter. Similar to the prior year, the provision was not material due to the continued valuation allowance on our global deferred tax assets. which limits our ability to recognize tax benefits from the loss. Net loss for the quarter was $1 billion, a $204 million improvement compared to a $1.2 billion loss in the first quarter of 2024. Loss per share was $2.52, an improvement from a loss of $3.07 in the prior year period.

We ended the quarter with cash, cash equivalents and investments totaling $8.4 billion. compared to $9.5 billion at the end of Q4. The decrease was primarily driven by the operating loss for the quarter.

Now let's turn to our financial framework for 2025 on slide 8. Our expectations for the full year 2025 remain unchanged from our initial guidance in February. We still expect total revenue in 2025 to be in the range of $1.5 billion to $2.5 billion with first half sales of approximately $0.2 billion, reflecting the seasonality of our respiratory vaccine business.

As a reminder, the wide range of our guidance reflects the uncertainties in vaccination rates, the competitive market environment, the size of the RSV market, and timing of licensure of our factories and product approvals in Australia, Canada, and the UK

As previously shared, while we filed three products with the FDA in 2024, since we don't know the timing of potential approvals, we are not including any new product revenue in our guidance range. Cost of sales is projected to be approximately $1.2 billion, reflecting continued improvements in manufacturing efficiency, and lower expected inventory write-offs, offset by increased costs associated with the go-live of our new manufacturing sites in Australia, Canada, and the UK

I'll now provide some perspective on the newly introduced global tariffs, those in action as of today have not had a significant direct impact on Moderna. All of our drug substance for the US market is manufactured at our facilities in Massachusetts. Our commercial drug substance has been shipped overseas for fill/finish operations before shipment to the final customers.

Internationally, our new plants in Australia, Canada and the UK are expected to be outlined in 2025 to supply local markets. Finally, material sourced from China are not material to our total cost base. R&D expenses are anticipated to be approximately $4.1 billion as we continue to invest in our late-stage pipeline while maintaining financial discipline. SG&A expenses are expected to be approximately $1.1 billion, reflecting a continued focus on efficiency while supporting our commercial execution.

While we are pleased with the cost reductions that we achieved in both R&D and SG&A during the first quarter of 2025, it is still early in the year, and we are not updating our full year expense guidance at this time.

That being said, it is a strong start to the year, and we are looking to accelerate additional cost reductions in 2025. We expect taxes to be negligible in 2025, and capital expenditures are projected to be approximately $400 million. And we still expect to end 2025 with approximately $6 billion in cash and investments.

Beyond 2025, we are announcing today our plan to drive an additional $1.4 billion to $1.7 billion of cost reductions by 2027. As part of our commitment to achieve our 2028 breakeven target on a cash cost basis. To that end, we are reducing our 2026 GAAP operating expense forecast from $5.9 billion to a range of $5.4 billion to $5.7 billion. This guidance includes $0.9 billion of noncash charges from stock-based compensation, depreciation and amortization.

Excluding these items, we now project a 2026 cash cost of approximately $4.7 billion at the midpoint of the range. We are also planning to reduce 2027 GAAP expenses to between $4.7 billion and $5 billion. with a 2027 cash cost of approximately $4.2 billion at the midpoint of the range, excluding stock-based compensation, depreciation and amortization.

Stepping back from 2023 to 2027, we are planning a total reduction in annual GAAP expenses of over $6 billion, which represents a 55% reduction over four years from $11 billion annually in 2023 to $5 billion or less in 2027.

The first $4 billion of GAAP expense reductions were realized in 2024 with the largest driver coming from reductions in our cost of sales, when we undertook a strategic initiative in the second half of 2023, to restructure our manufacturing footprint to better optimize pandemic level demand of our COVID vaccine. We also reduced SG&A by 24% from 2023 to 2024 through a variety of cost-out initiatives throughout the company, and R&D declined 6% year-over-year to $4.5 billion in 2024.

While we are continuing to drive additional cost reductions and efficiency gains in both cost of sales and SG&A, the largest future source of cost reductions will come from R&D. which currently represents nearly two-thirds of our expense base. This projected decline in R&D expense will come from the completion and wind down of our ongoing Phase 3 trials. procurement savings from contract renegotiations and other process efficiencies.

In summary, we are encouraged by the progress we've made in our cost-out initiatives to date. As Stephan mentioned, we now have had three consecutive quarters of double-digit year-over-year declines in combined R&D and SG&A expenses. Our teams continue to identify and act on new savings opportunities, which gives us the confidence in meeting our new 2026 and 2027 cost targets.

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

Stephen Hoge - *Moderna Inc - President*

Thank you, Jamey. Good morning or good afternoon, everyone. Today I will review progress across our pipeline.

Slide 11 is a review of our prioritized pipeline, which is introduced at our R&D Day last September. As you know, we have since filed for regulatory approvals for three of these programs. our next-generation COVID vaccine in mRNA-1283, our RSV vaccine for high-risk adults aged 18 to 59 mRNA-1345 and our flu plus COVID combination vaccine for individuals aged 50 and over are mRNA-1083.

As part of our ongoing portfolio optimization, we've made a strategic decision to deprioritize the flu covid combination vaccine for younger adults, those aged 18 to 49.

While we remain committed to the long-term potential of combination respiratory vaccines, we are going to be focusing our efforts on combination vaccines in the older adult population for now. At the same time, we are excited to announce the advancement of our oncology pipeline with the addition of the Checkpoint program.

The prioritization of this Phase 2 program is based on our early but encouraging data and is consistent with our strategy to build our therapeutics pipeline, particularly in oncology. We are targeting filings for Checkpoint and the other six programs on the right-hand side of this slide by 2028, subject to notes to data and regulatory consultations.

Moving to slide 13, which outlines the latest development in our late-stage respiratory portfolio. As I just mentioned, we submitted regulatory filings late last year for three programs. Our next-gen COVID vaccine has a PDUFA date of May 31. The age group expansion for our RSV vaccine has a PDUFA date of June 12, and we look forward to decisions on both products in the coming months.

For our flu COVID combination vaccine, we received a November 2025 PDUFA date. However, following feedback from the FDA during the review, the flu vaccine efficacy data will now be needed to support the application.

As a result, we now expect to review timeline to be extended into 2026 and be dependent upon positive Phase 3 efficacy results from our ongoing food vaccine trial. and the addition of these data to the submission.

And on that point, our stand-alone flu vaccine candidate, mRNA-1010, is in its Phase 3 efficacy study. And due to the intensity of the current flu season, has now exceeded the required number of cases to support the interim efficacy analysis, which we expect to complete now by this summer.

Now turning to our nonrespiratory vaccine and rare disease portfolio. Our for our CMV vaccine, we recently presented durability data from our Phase 2 study at the SMID Conference, demonstrating that mRNA-1647 continues to elicit robust antibody responses for three years post vaccination, showing very strong durability.

We also had the opportunity to share these findings along with an overview of our CMV program at the inaugural CMV vaccines Work Group as a part of the April ACIP meetings. We're encouraged by the establishment of this work group, which reflects the growing recognition of CMV as a significant public health concern and a commitment to reducing the disease burden of CMV.

Our Phase 3 CMV efficacy study for mRNA-1647 continues to recruit cases. We remain blinded to the study results at this time and expect the final efficacy analysis to come later this year. For norovirus, we are pleased to note that the FDA clinical hold for our Phase 3 trial was lifted during the quarter. The study is fully enrolled in the Northern Hemisphere, and we are continuing to enroll in the Southern Hemisphere.

Phase 3 FC readout for norovirus is dependent upon case accruals. And given the uncertainty of that timing, the targeted approval could be in 2026 or 2027, depending upon that readout. We expect to have more clarity on the pace of case accrual and potential readout timing later this year.

In rare diseases, our probiotic acidemia, or PA program is currently in a registrational study. We've made good progress with regulators and with enrollment. Following review of program timeline and other aspects of the launch, we now anticipate a 2027 approval. Similarly, for methylmalonic acidemia or MMA, we've finalized the registrational study design with the FDA, and we plan to initiate that trial in 2025. We expect the potential for approval for M&A in 2028.

We continue to advance our oncology portfolio with significant progress across our individualized neoantigen therapy program, Intismeran, our Checkpoint program, and our early-stage oncology programs. In collaboration with Merck, we have several late-stage studies underway for Intismeran. As a reminder, the Phase 3 trial in adjuvant melanoma is now fully enrolled. We also have two Phase 3 studies in non-small cell lung cancer, both evaluating Intismeran in combination with KEYTRUDA in patients with and without prior new adjuvant treatment.

Additionally, we're conducting randomized Phase 2 trials in adjuvant high-risk muscle invasive bladder cancer and adjuvant renal cell carcinoma. I'm happy to announce that the Phase 2 adjuvant renal cell carcinoma study is now also fully enrolled. We're also expanding the scope of our Intismeran program into earlier stages of disease, with the addition of a new Phase 2 study that moves beyond the adjuvant setting. This study evaluates Intismeran as monotherapy or in combination with BCG, the standard of care in high-risk non-muscle invasive bladder cancer and will help us explore Intismeran's potential in earlier disease settings beyond the adjuvant landscape.

As I mentioned a moment ago, we have prioritized advancement of our Checkpoint program based on encouraging early clinical results. The program is currently being evaluated in a Phase 2 study for both first-line metastatic melanoma and first-line metastatic non-small cell lung cancer. I'll review the details of that program on the next slide. We're also advancing two novel cancer antigen therapies to the clinic. mRNA-4106 is a tumor-targeted antigen therapy designed to direct the immune system against multiple shared tumor antigen.

The first patient has been dosed in a Phase 1 study in solid tumors that is assessing safety, pharmacodynamics, immunogenicity and preliminary efficacy for the program. And we have an open IND for mRNA-4203, which is designed to boost the activity of an engineered T-cell therapy to improve its persistence and effectiveness. This program is being developed in collaboration with Immatics. These cancer entogen therapies, Checkpoint mRNA-4106 and mRNA-4203 are off-the-shelf therapies in contract with intesmarin, which is an individualized cancer treatment. These programs reflect our growing oncology pipeline with more coming soon.

Now let me provide an overview of the Checkpoint program, mRNA-4359, starting with its mechanism of action. Checkpoint is designed to help a patient's immune system recognize and attack tumor cells by encoding mRNA-based cancer antigens for PD-L1 and IDO. The therapy trains the immune system to recognize upregulation of PD-L1 and IDO by cancer cells and immunosuppressive regulatory T cells. By combining this targeted immune activation therapy with checkpoint inhibition with traditional antibodies such as KEYTRUDA, we aim to enhance the antitumor response. overcoming in innovation and improving the depth and durability of responses.

Checkpoint is being evaluated in a Phase 1/2 clinical study, which is now moving and moving forward and enrolling the Phase 2 portion. This study is designed to assess the safety and tolerability of checkpoint, both as a monotherapy and in combination with KEYTRUDA in first-line metastatic non-small cell lung cancer and first-line metastatic melanoma. Key efficacy endpoints will include objective response rate, disease control rate, duration of response and progression-free survival. It is an open-label study.

In addition to clinical outcomes, we are evaluating T cell profile changes, both in the peripheral blood and within the tumor microenvironment to better understand mRNA-4359 mechanism of action. We shared early Phase 1a data at the ESMO Medical Congress in late 2024, and we're excited

and looking forward to sharing the data from the Phase 1b portion of the study at a medical conference later this year. Based on the early encouraging results, we plan to expand checkpoint into multiple additional cancer indications.

With that review, I will now hand it over to Stephane.

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

Thank you, Stephen and Jamey.

We are focused on three priorities. Priority one, to drive sales of approved products. Priority two to focus on our late-stage pipeline to drive sales growth and diversification. Priority three, to deliver cost efficiency across the entire business. Our first priority is to drive the Spikevax and RSV vaccines. We entered 2025 with two approved products which puts us in a better competitive position compared to the beginning of 2024. With our ability to now offer RSV for a full season, we expect to better compete in the respiratory vaccine market. In a recent international media approval should add to sales this year.

Priority two. We are focused on delivering up to 10 product programs, which we believe will drive sales growth. Together, this 10 anticipated product targets a total addressable market of over $30 billion. As Stephen discussed earlier, we have taken some of our priority programs. For the combination of flu and COVID in age 50 and older, we expect the additional several -- some efficacy data coming soon. For compiling, we'll extend the review and approval timeline to 2026.

For Norovirus, the grant timing is dependent on cash accrual, which will mean the potential 2026 or 2027 approval. We are very pleased with the addition of Checkpoint AMC to our new prototype pipeline, mRNA-4359. And finally, for PA, MMA we estimate approvals in 2027 and 2028, respectively. Priority three, drive cost efficiency across the entire business. We've demonstrated our commitment to cost discipline through reduction achieved in 2024 and 2025 to date.

We remain confident in our ability to further streamline our operating structure for the remaining of 2025 through 2027. We are pleased to announce today the 2027 cash cost target of $4.2 billion giving us additional confidence in achieving our cash breakeven target in 2025. [Proft product] program, we expect important milestones. We filed for approval for three products in 2024 for next-gen COVID, mRNA-1283, or as vaccine for high-risk 18 to 59-year-olds. We look forward to regulatory vision on this. For flu and COVID combination vaccine, we expect an extended review timeline pending positive stand-alone through efficacy data and submission with expecting a '26 approval.

For CMV, we look forward to having the final results of our Phase 3 vaccine efficacy study in 2025. We have exceeded the cash accrual goals for full efficacy study and expected without by this summer. On norovirus vaccine is in Phase 3 and the timing of our data will be subject to case accrual. In oncology, the return of our ongoing in this Intismeran Phase 3 adjuvant melanoma trial will be subject to even the course, and we expect to present our Phase 2 five-year durability data in adjuvant melanoma next year.

As mentioned before, we are very excited by the addition of the Checkpoint AIM-T productized portfolio, and we look forward to sharing data at medical meeting later this year. For PA, we are already generating data for registrational study, and we expect to start a registrational study for MMA this year.

I am very thankful to our team for our progress achieved so far across the commercial organization, our late-stage pipeline, and great cost reduction efforts across the company.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Salveen Richter, Goldman Sachs.

Salveen Richter - *Goldman Sachs Group, Inc. - Analyst*

You noted that based on FDA feedback for Phase 3 Flu efficacy data, you now expect an extended review time line and you're targeting approval in 2026. Could you comment any further on your interactions with the FDA and why they decided to require this? And more broadly, just to the potential risk of the vaccine business outlook under the new administration?

Stephen Hoge - *Moderna Inc - President*

Thank you, Salveen, for the question. So first, on the narrow question of the flu study, we have moved forward very quickly in enrolling cases as the FDA and everybody is now aware and actually in that flu efficacy study, which we originally thought might be a two-season efficacy study, we now know that very shortly here, we will have a readout with a very large number of cases in a 40,000-person study.

And since that we'll speak to the potential value of our flu component it makes good scientific sense that, that would be a part of the review that's going on for our flu COVID combination.

I'll remind you, we had already demonstrated efficacy for the COVID component. And really, now we're almost sitting on top of that flu vaccine component. So for a whole bunch of, I think, quite reasonable scientific reasons. It makes sense that we review that as a part of the combination vaccine study, the implication of that is we'll have to complete that review, obviously, hopefully, see a positive result and then submit it to the current BLA for the mRNA-1083 program, that will inevitably lead to some form of clockstop and extension of the review time lines.

And so we're excited to see those results in flu. We think they will -- we hope they will be constructive for the flu COVID program and look forward to submitting them -- sharing those results first and then summing them once we have them. As far as more broadly, a question about our interactions with the FDA across multiple submissions, those continue business as usual from our side. We continue to have productive exchanges across all of our ongoing final reviews that includes our 1283 program, the RSV program. We continue to be engaged in anticipating seasonal program -- seasonal composition update for this coming fall.

And then obviously, I've just spoken to what's happening in the flu COVID combination space. So from our perspective, we are grateful for the ongoing collaboration work, and we'll continue to make sure that we provide all the data required to conduct a diligent review of all of our products in our portfolio.

More broadly, I guess the question to outlook, and I invite others to sort of add if I miss anything, but we continue to see an opportunity -- a real need for COVID vaccination particularly this coming fall. And we'll remind that through this winter season, we still saw thousands of deaths in the United States, actually about 1,000 deaths a week during the peak winter months from COVID-19. The overwhelming majority of which were from folks who had not been vaccinated, but were older Americans and had risk factors.

And we do believe that vaccines have a unique opportunity to prevent those deaths at those hospitalizations. There was actually a publication of Denmark just this week showing that this past year, our updated vaccine composition was 96% effective at preventing death, 85% effective at preventing hospitalization this year.

And so we do believe that there is a need, and we believe there's an opportunity with vaccines to play an important role in public health, ultimately, people need to make their own decisions about that. So our focus right now is making sure that those products -- our products are available for American and for in markets around the world for the coming fall cold season.

Operator

(Operator Instructions) Eliana Merle, UBS.

Unidentified Participant

Hey this is Jasmine on Eli. Thanks so much for taking our question. So what's the latest on your thinking, whether it's seen INT Phase 3 data in 2026 is still a reasonable expectation. I'm wondering what your plans are for new trials, expansions and other indications for both INT and the newly prioritized Checkpoint?

Stephen Hoge - *Moderna Inc - President*

Sure. Thank you for the question. So first, I'll remind you that the Phase 3 melanoma study, it reached its target enrollment in September of 2024. Last year, we announced that. Given the historical event rates that would lead us to expect that we would have accrued enough events for at least the first analysis of efficacy in 2026. And so we are still ultimately waiting for events, and it will be event-driven, whether that analysis happens. But based on our prior experiences, both in Phase 2b and the other expectations, we still believe the '26 readout is possible, it's not likely.

For other indications, we haven't provided updates, obviously, for the non-small cell lung cancer study. We're really pleased with that enrollment, but we haven't provided a specific update on timeline there. And for the Phase 2 studies, we did, as you noted, recognize that we've now fully enrolled the randomized study in renal cell carcinoma, which is exciting, because that randomized study has a chance of a readout. We have not, with our partner, Mark guided when we expect that will be, but I will note that events do accrue relatively quickly in that indication in that population.

So we'll look forward to that. We will continue to look to expand perhaps into monotherapy spaces, both ourselves and Merck have indicated that, and we have an instance of that. that we're bringing forward today. There will hopefully be others, but I will defer from commenting on them until we and Merck are ready to announce that we've started those efforts.

On the question of Checkpoint, we are obviously encouraged. We would like -- we look forward to sharing the data that's the basis of that encouragement at an upcoming medical meeting. because we've been looking at that program very carefully in its Phase 1b portion of the study, which I'll remind you is a combination with antibody checkpoints to see whether or not we can see a synergistic effect.

And we're currently moving forward in at least two histologies that we talked about today. So that first-line non-small cell cancer in the first-line metastatic indication Obviously, we have also been looking at it in second-line indications as a part of that Phase 1 program, and we'll continue to do so. We will add additional histologies in the future, but we're not ready to announce any today.

Operator

Tyler Van Buren, TD Cowen.

Tyler Van Buren - *TD Cowen - Analyst*

Just at the risk of being repetitive here, and just to be clear, more specific, given how close we are to the PDUFA, it's business as usual for the 1283 review. Can you talk about just how interactions are going for that program and what your confidence is in approval given the new leadership and recent denial of the Novavax program?

Stephen Hoge - *Moderna Inc - President*

Yeah. I mean, obviously, I can't kind of comment on other programs because I'm not familiar with what's going on there in those confidential exchanges. But I can speak to ours, which is it really has been business as usual.

\There are lots of exchanges of scientific information. We really view it as our responsibility to provide high-quality data to all of our regulators, including the FDA so that they can conduct their assessments. To date, those assessments have, we believe, been constructive and positive. And we have seen no sign that we're in -- that there's any question about our ability to make the existing PDUFA date.

Now again, review is ongoing, and we have to defer to what questions may come from the FDA or others as we move forward. but it really has felt like business as usual.

Operator

Michael Yee, Jefferies.

Unidentified Participant

This is Diana on for Mike. Just a quick question about a recent media article that came out yesterday. regarding how vaccine trials would be run that they would now require to be run against placebo. Just wanted to get your thoughts about that. What do you think that will do to enrollment? Will it be harder enroll easier -- and is that going to be required, do you think, for all respiratory vaccines, specifically covered for you guys or just newer vaccines such as CMV or any others that you're working on in the product line?

Stephen Hoge - *Moderna Inc - President*

Thank you for the question. So we're -- I would say comment on a policy change that either hasn't happened or that we haven't been communicated directly to us. I will note that as you did our COVID vaccine, our RSV vaccine, our CMV vaccine, our norovirus vaccine, these are all conducted as placebo-controlled studies.

And for many of the other products in our pipeline, there are portions of their development that happened in placebo-controlled studies, usually earlier clinical development or in certain populations. for instance, our COVID vaccine was studied in children in a placebo-controlled context.

So it will really depend upon ultimately what the FDA and HHS feel is appropriate and their guidance at a program-by-program level of what that will require. Our responsibility as a manufacturing and a drug developer is to make sure that we provide the data that regulators and public health officials feel like they need so that they can stand behind our products. And so we will -- we will absolutely engage constructively and making sure we understand what those needs are and that we fulfill them.

Operator

Terence Flynn, Morgan Stanley.

Unidentified Participant

This is Chris on for Terence. Just one quick question on the COVID strain selection. So given the regulatory uncertainties, can you please elaborate on the process for the COVID strain selection moving forward?

Stephen Hoge - *Moderna Inc - President*

Sure. I will answer from a global perspective, I will start by saying in every instance, it is up to our regulators in now all of these countries to tell us as manufacturers, what updates they may or may not want for the coming year. I will note that some years, flu does not update all of its strains for sure. in some years been so far with COVID, we've had updates every year. There are continuing evolving strains that we are tracking that we think might justify an update this year -- but that decision we're really lie with a set of regulatory bodies.

First, we will probably, based on timing here from WHO and EMA and other international regulators. And then we would expect to also hear probably at the same time from the US FDA. The process is really up to them how they choose to ultimately conduct their selection process on whether or not they want to do a strain update for this year and what the composition will be, I'll defer to each of those individual regulators. But we would expect within the next month if we follow the same process that we have in prior years to hear from all of them about what they'd like to see us deliver for the fall for their respective countries.

Operator

Cory Kasimov, Evercore ISI.

Cory Kasimov - *Evercore ISI - Analyst*

I wanted to ask you about the flu COVID combination and the updated timing you have there. You may not know yet, but is it your expectation that you would need to refile that with the updated flu efficacy data? Or could you just submit that data as a -- I guess, what would be considered a major amendment, in other words, potentially delaying this by just three months and enabling a potential FDA decision in early 2026 as opposed to later in the year?

Stephen Hoge - *Moderna Inc - President*

Thank you for the question. And I think the short answer will be, we don't know. It will ultimately depend upon consultation with the FDA of what they would prefer the approach to be. It is totally appropriate to submit that data as an amendment to the BLA.

It could also be from a pragmatic perspective, it makes sense to update more broadly the BLA submission with it, which could result in resubmission. We'll just go forward with whatever feels like the most pragmatic approach and ultimately, the one that the FDA guides us to do.

I will say that absent that, there is a lot of other information in the current file, including the performance of the COVID component, obviously, things on manufacturing, the broader immunogenicity and safety data set from the pivotal Phase 3 for the flu covid combo and the review of all that information is progressing.

And so there are reasons why amending with the flu efficacy data may be the most pragmatic approach. But again, it will depend upon consultations with the FDA, which will only be appropriate to do after we have that flu efficacy data in hand.

Operator

Courtney Breen, Bernstein.

Courtney Breen - *Sanford C. Bernstein & Co. - Analyst*

The main kind of focus for us is really on kind of some of the new cost cutting that you guys have announced today. What we would really like to understand is kind of what particular milestones or expectation changes drove you to increase the cost-cutting program. I think you've been quite explicit in the past that you'll be looking for top line signals to drive new changes there?

And then kind of the second question is what components would you point to as being kind of those where you've felt you've been able to flex to enable kind of some of that cost cutting that we're now into additional cost cutting that we're now anticipating in 2026 and 2027 from last expectations?

James Mock - *Moderna Inc - Chief Financial Officer*

Yeah. Thanks for the question, Courtney. As to the first piece in terms of what are the milestones or what's changed. A lot of this is nothing has changed. So we were expecting and we've been indicating that we are right now going through a lot of Phase 3, large Phase 3 trials. In RSV, CMV, norovirus, our combination vaccine, flu and many of those just ramped down and are completed by 2027. And we had never really given guidance for 2027. So much of this was just extending our guidance out a year and indicating just what that R&D level will be.

The second thing is as to a milestone. I mean, yes, it's an uncertain environment. So there's nothing from a revenue perspective that we have seen that would indicate that we need to do this, but we need to focus on what we can control. and that is our cost base. And as we look out to 2027 and 2028, we felt that it was appropriate to get our cash cost to about $4 billion to make sure that we fulfill on our commitment to breakeven by 2028.

Now as to the how, I already mentioned the large majority of it, which is the Phase 3 trials, but we have been on a cost efficiency program for the last couple of years, as I mentioned in my prepared remarks. So there's much to do and the teams continue to identify additional opportunities in procurement. We're using digital tools or relooking how we get work done.

And so we just think that there's a lot that we can go do and our -- that's why we came out with new 2027 guidance. Just as we look out, some of this is as expected. Some of this is the continued improvements that our teams see and we look forward to executing on it and fulfilling our commitment to breakeven by 2028.

Operator

Myles Minter, William Blair.

Unidentified Participant

It's Dick on for Myles. First, for norovirus, have you guys identified the source of the GBS case that was originally identified the FDA? And have there been any additional cases of GBS noted in the Northern Hemisphere or Southern Hemisphere trials?

And then second, for Intismeran for the study in which you quantified the number of T cell clones induced, we're curious how you're comparing that to BioNTech product and whether you use the same analysis pipeline that they've use for their quantification for your sequencing data.

Stephen Hoge - *Moderna Inc - President*

Thanks for both questions. So first, yes, on the norovirus study, yes, we're pleased that the clinical hold has been lifted. Obviously, what means we've sort of satisfied any of the questions and importantly, updated materials that were from an informed consent perspective, all that's out there. We have not seen an additional GBS case, obviously. That's encouraging, but not necessarily unexpected. It is unfortunately rare about when it does occur.

As far as causality, we may never know -- I will remind you that there are GBS cases in the background population, particularly in older adults that happen fairly regularly. several per hundred thousand, and we're enrolling these large 25, 000, some 50,000 person studies over multiple years. We do see occasional GBS cases actually on the placebo arms of these studies. and now we've seen one in active. It's possible that it's related to the vaccine. It's possible that it's not. And we are working hard to assess causality, but you can't really ever get a direct length.

What you really can do though is characterize the frequency of these things and make sure that people are aware of them. And as a part of our ongoing Phase 3 norovirus study, we'll continue to very actively monitor for additional cases of GBS, we certainly hope we don't see any either on the placebo arm one. But all of that pretty -- we're pretty encouraged, again, just to be off-clinical hold and moving forward with enrollment and hopefully, moving forward with that program.

The Intismeran question. So I can't speak to the way BioNTech had run their pipelines. Obviously, we're not deeply familiar with it. We are really encouraged by the clonality that we're seeing in TCRs. I think it's some evidence that we're really deepening and broadening the response and that those are matched by what's happening in the vaccine, that sort of translational data that ultimately is supportive of what is the really exciting evidence of efficacy that we've already seen from that study.

And I think that, that's ultimately just giving us some of the vibe, but the what was the remarkable hazard ratio improvement that we've reported both at ASCO last year and that we'll look to be updating as we continue to follow that Phase 2b study.

Operator

Gena Wang, Barclays.

Gena Wang - *Barclays - Analyst*

I have two quick questions. One is when we look at the COVID revenue this quarter, the US was only $29 million and seems only a fraction of the Pfizer US revenue. So any concerns of the future market share change? And the second question is regarding the flu vaccine interim data in Summer '25. Could you please share your total events that you plan to achieve?

James Mock - *Moderna Inc - Chief Financial Officer*

So Gene, I'll take the first question. I'm not sure if we heard the second question, so we might ask you to repeat that. Yes. I mean we looked at the Q1 revenue for ourselves and our competitors. And all we can point everybody to is the actual script data. And the script data through the first part of this year is really pretty similar to last year and 38% market share. And even if you go back to last year and you normalize our revenue in the US, we've talked about in the past, $1.7 billion, take out the gross to net changes. It's really $1.5 billion. That across that marketplace is a 40% market share.

And that's exactly what we see, I guess, 38% scripts data. That's what we see through the first half. I would also say that our customers are trying to manage their working capital better. So their inventory levels are down, so I can't comment on other companies' revenue, but I can comment on what we see in the actual marketplace from a script perspective.

Stephen Hoge - *Moderna Inc - President*

And Gena, we didn't quite hear the second question. Could you just repeat it, please?

Gena Wang - *Barclays - Analyst*

Of course. So the second question is regarding the flu vaccine, the ATC data in Summer '25. I don't know if you would be able to share regarding the total events and the stats around it that you plan to achieve?

Stephen Hoge - *Moderna Inc - President*

I don't think we have provided any guidance on it. It is obviously a very large number cases because there was quite a large (inaudible) year. But at this point, I don't think we're going to provide any guidance. We're ultimately just going to conduct that analysis literally the season is over, and we'll try and share those results and then obviously explain them once we've released that.

Operator

Jeff Meacham, Citigroup.

Unidentified Participant

Good morning. This is Dave on for Jeff. Just broadly thinking about the recent ACIP meeting. Just wondering if you could comment broadly on some of the comments that you made, namely on CMV and you need for durability data and its implementation challenges and for COVID perhaps the possibility to move from a universal recommendation to when it's risk based. And then separately for the new checkpoint program, given the cost cuts that you guys are not implementing, could you please share perhaps any potential to out license or even partner program in the future.

Stephen Hoge - *Moderna Inc - President*

So first on CMV, look, I think we're -- we do recognize for that vaccine we'll want to see good durability. 5, 10 years would be ideal if not longer, because at the end of the day, what you're trying to do with CMV is seroconvert people so they can control and prevent really a substantial infection with the virus. The durability data we've got to date actually looks really strong.

So if you look at the antibody titers through 3 years now and similar cell-mediated immunity, but focusing on the neutralizing titers, they're essentially flat 2 to 3 years. And if you model that forward, it does look like it's going to meet our objectives for really durable immune responses.

That's incredibly encouraging. We've seen in a related program in EBV, real durability and viral suppression. We previously reported on that. And so we're pretty -- we're feeling pretty optimistic about the performance of the latent vaccine platform and specifically CMV and our ability to achieve durability.

As far as the ACIP conversation on that, we were actually quite encouraged by how constructive people are about the need for a CMV vaccine that any efficacy there will be seen as valuable because at the end of the day, this virus is a scourge, and so while durability was raised, we actually think we've addressed that question and the question of efficacy, we feel pretty aligned with that conversation and optimistic that our current results will be positive.

The question on COVID and changes in recommendation. Look, at the end of the day, it is for public health officials to decide how to use our products, our responsibility to bring forward the data that allows them to make that decision. risk-based decisions have been applied in other countries. Certainly, if you look at the types of populations that have been identified, those that are older adults, 65 plus those who have any risk factor. In fact, 74% of Americans had risk factor for severe COVID-19, including under the age of 64, that there was real support for that.

And then there was general support for let people decide I think that was seen in the polling of the ACIP working group. So for those even without risk factors that might want to protect themselves again COVID, they should the right to do it. I will note that if you look at death and hospitalization data, it tends to be in the older adults. It tends to be in the in those with risk factors.

And so it makes sense that we will want to encourage strongly vaccination in those populations. Again, 1,000 Americans a week dying through this past winter is more than died in traffic accidents per week. It's really something we must address.

As far as the Checkpoint program is concerned, -- we have -- we're really encouraged by that data. We're moving forward. At this point, one of the reprioritizations you saw in our pipeline is that we decided not to invest in a pivotal study for younger adult combination vaccines. That's the 18- to 49-year-old flu COVID and combo vaccine.

And really, what you should interpret with that is that we are reprioritizing that investment into our oncology pipeline based on the emerging data. It's not any disservice to the -- or any problem with the 1083 program, we're actually really encouraged by it, but we're going to focus there on older adults and those that are higher risk and we're going to take the opportunity to reinvest that money in a Checkpoint, which we are encouraged to move forward with ourselves.

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

Yes. And maybe just to add to Stephen's point because I think it's an important strategic consideration. As we've said at several days respiratory is a very important franchise for us, whereas Stephen said, incredible medical needs for many, many years to come, unfortunately, for the patients. R&D costs as those Phase 3s are behind us, R&D costs in respect are coming down. That business is generating cash flow. We don't need to invest in manufacturing. And as Stephen said, we really want to be thoughtful about deploying that capital to about oncology.

We are very excited about our Intismeran programs, of course, but as Merck is funding half of it. And so that's why when we see opportunities in the clinical data we are seeing on Checkpoint we are able to pivot very quickly, which we think is very important to really have a company with a strong respiratory business, joining cash and investing in growth on therapeutics. That's where we were going.

Operator

Luca Issi, RBC CM.

Unidentified Participant

This is Shelby on for Luca. Maybe following up on the political landscape. RFK is on record arguing there is no evidence that a single antigen vaccine ever worked for respiratory diseases. He also claims he is working on multiantigen vaccines. Do you know what he means by that? And also, maybe bigger picture, how confident are you that your upcoming PDUFA will be reviewed based on the risk benefit profile of the molecules and not political agendas. Any thoughts much appreciated.

Stephen Hoge - *Moderna Inc - President*

Thanks for the question. As far as the Secretary's statements, I think you'd have to refer those questions to him. I can't comment because ultimately, it will depend upon his perspective. I will note that we have products that have been approved that had demonstrated efficacy. And so we'll continue to provide data hopefully, in support of that because we do ourselves believe that the clinical trials we run really to support the benefits of our products, including those that are single antigen, and we have some multi-antigen products.

I'll remind you that CMV is a seven mRNA massive multi-antigen product, as is EBV as are many of our other vaccines. And so we are -- we do believe that sometimes single antigen makes sense and some at multiple antigen make sense, and we do both. As far as the question on our PDUFA date, we -- as I said a moment ago, we continue to have constructive exchanges of data and information with the FDA in the review of all of our files, we've also been participating in the review of the information with the ACIP CDC working groups that ultimately also recommend these products.

Our responsibility is to make sure they have the information they need to do a risk-benefit analysis to follow the science where it leads. We are confident in the data we have. In the case of our next-generation COVID vaccine, I'll point to the fact that, that is an 11,000-person large, multiyear randomized efficacy studies.

And we think it is a really strong demonstration of the potential for that product to help patients against COVID-19. And so we're quite enthusiastic about it. Most of our other files include similarly large or larger Phase 3 randomized studies. It's quite a lot of information to get through.

And our job is to make sure that we present it objectively to the agencies so they can conduct its reviews. We remain confident that those reviews will be consistent with prior practice. And again, it has been business as usual for the first half of this year for us.

Operator

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

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

Thank you so much for joining us today. As you can see, we are really focused on executing on our strategy. Thank you for participating in the call. We look forward to speaking to you in the coming days or weeks. Thank you. Have a good day.

Operator

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