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OVERVIEW:

Company Summary

REFINITIV

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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the Moderna third 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. Please go ahead.

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

Thank you, Kevin. Good morning, everyone, and thank you for joining us on today's call to discuss Moderna's third quarter 2025 and 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 turn the call over to Stephane.

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

Thank you, Lavina. Hello, everyone. Thank you for joining us today. I will start with a quick review of the quarter. Jamey will present our financial results and outlook, Stephen will review our commercial progress, and clinical programs and then I will share our key value drivers as we look ahead before we take your questions.

In the third quarter, our revenue were $1 billion, driven by sales of our free approved vaccines, Spikevax (inaudible). The net loss for the quarter was $200 million. We ended the quarter with $6.6 billion in cash and investments. We remain highly focused on financial discipline. I'm pleased to

announce that continued cost reduction efforts across the company in the third quarter of 2025 led to a 34% reduction of cost of sales, R&D and SG&A combined compared to the third quarter of 2024.

During the quarter, we made good progress across our three strategic priorities. Our first priority is driving use of our commercial products. For Spikevax, our original COVID vaccine, we received approval in 40 countries for the seasonal 2025-2026 train update. And (inaudible), our new COVID vaccine was approved this year by the FDA. We also filed and received approval for the 2025-2026 strand update in the US, making this the first season that mNEXSPIKE is available in the United States. We also received approval for mNEXSPIKE in Canada.

For (inaudible) vaccine, mRESVIA will continue to gain regulatory approval and mRESVIA is now approved in 40 countries. We have a strategic partnership with three countries, Canada, the UK and Australia, where we have established manufacturing facilities and secured a multiyear offtake agreements. In each of these countries, we have achieved important milestones. In Canada, we delivered the first made in Canada, mRNA vaccines to the Canadian government for used this season. In the UK and Australia, our facilities were granted licenses by their respective regulatory agencies.

Second priority, advancing pipeline to grab sales growth. We announced in July, positive Phase III full efficacy data which we believe will advance both our flu vaccine program, mRNA-1010 and our flu plus COVID combination program, mRNA-1083. For the flu plus COVID combination program, our filing continues to be under review by the European Medicines Agency.

In Oncology portfolio at the European Society of Medical Oncology, ESMO, Congress in October, we presented encouraging Phase Ib data for cancer antigen therapy, mRNA-4359. Unfortunately, we also announced recently that despite the progress made by the Safety Community in understanding the CMV virus, our CMV program did not meet its primary efficacy endpoints for (inaudible). We will discontinue the development of our CMV vaccine in this indication.

Third priority, executing with financial discipline. The team continues to diligently advance our cost improvement program. Over the last four quarters, Q4 2024 to Q3 2025, we delivered a $2.1 billion improvement in costs across cost of goods, SG&A and R&D versus the prior four quarters. I want to thank the entire Moderna team for this great achievement, and we continue to work on prioritizing our ID pipeline, growing productivity equaling by the use of more digital tools including a large number of GPs, also better pricing with our suppliers across the entire company.

Thanks to this good progress and momentum, we've reduced projected 2025 cash cost by approximately $500 million since just the last quarter investor call in August 2025, and by approximately $900 million since the beginning of the year.

With this, I will hand over to Jamey.

James Mock - *Moderna Inc - Chief Financial Officer*

Thanks, Stephane, 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 2025. Let's start by reviewing our commercial performance, which you can follow on slide 7.

Year-to-date, total revenue was approximately $1.3 billion, with $900 million from the US and the remainder from international markets. In addition to product sales, revenue also includes collaboration, grant and stand ready revenue associated with our strategic partnerships.

For the third quarter of 2025, our total revenue was $1 billion, US revenue was $800 million in the third quarter, the vast majority of which was from our COVID vaccines, which included the successful launch of our new COVID vaccine, mNEXSPIKE. Stephen will give more detail on the US COVID vaccination season at a moment.

Revenue outside the US was $200 million. Approximately half of international revenue in Q3 was delivered to Canada. -- where we began executing on our strategic partnership through our in-country manufacturing facility. As a reminder, we have similar strategic partnerships with the Australian and UK governments and expect to begin shipping locally manufactured product in 4Q '25 and 1Q '26, respectively.

For the full year 2025 outlook, we are narrowing our revenue range to $1.6 billion to $2 billion from our previous guidance of $1.5 billion to $2.2 billion. For the US market, we expect fourth quarter sales of $100 million to $400 million. This would bring our updated full year US revenue guidance to $1 billion to $1.3 billion versus our prior guidance of $1 billion to $1.5 billion.

Our original guidance assumed year-over-year revenue to be flat to down 33%, excluding onetime items. Our updated guidance now assumes a year-over-year decline of 15% to 33%. COVID vaccination rates remain the largest variable to this range, which Stephen will walk through in a moment.

For international markets, we now expect revenue to be between $300 million and $400 million in the fourth quarter, bringing the full year to $600 million to $700 million versus our previous guidance of $500 million to $700 million. We have a tighter range on our international sales as most of these sales are for contracted volumes leaving delivery timing and file vaccination rates as the only remaining variables. Moving to slide 8, I will review our 3Q financial results in more detail.

Total revenue was $1 billion in the quarter, as I just discussed on the prior page. We had net product sales of $973 million and other revenue of $43 million from grants, collaborations, royalties and stand ready fees. The 45% year-over-year decline in revenue was expected and primarily reflects lower COVID vaccine demand.

It's also worth noting that last year's third quarter included approximately $140 million from a true-up adjustment to prior period sales provisions. That benefit did not repeat in Q3 this year. Cost of sales for the third quarter was $207 million, representing 21% net product sales for the quarter. This was a 60% year-over-year decrease in our cost of sales from $514 million in Q3 last year.

The improvement was driven by lower inventory write-downs, reduced unutilized manufacturing capacity and lower volume. Overall, these results reflect the productivity gains and the efficiency improvements we've achieved in our manufacturing operations.

R&D expenses in the third quarter were $801 million, a 30% decrease from last year. The reduction mainly reflects lower clinical trial costs as we completed several large Phase III studies in our vaccine portfolio as well as efficiency gains across the organization. Last year's results also included an expense related to the purchase of a priority review voucher.

SG&A expenses were $268 million in the third quarter, a 5% decrease year over year. The decline mainly reflects lower consulting and external service costs across multiple functions, along with reduced digital and facility spending. These savings reflect the cost discipline we've built into the organization and our continued focus on streamlining how we operate.

Our income tax provision for the quarter was immaterial, consistent with the prior year. We continue to maintain a global valuation allowance against the majority of our deferred tax assets, which limits our ability to recognize tax benefits from losses.

Net loss for the quarter was $200 million compared to net income of $13 million in Q3 2024. Loss per share was $0.51 compared to earnings per share of $0.03 last year. We ended Q3 with cash and investments of $6.6 billion, down from $7.5 billion at the end of Q2. The decrease was primarily driven by seasonal impact to working capital. With that, let me take a minute to share the progress we've made on our cost reduction goals.

As a reminder, our original target this year was to reduce our GAAP operating expenses from $7.2 billion in 2024 to $6.4 billion in 2025. On a cash cost basis, excluding stock-based compensation, depreciation and other non-cash charges, that represented a decrease from $6.3 billion in 2024 to $5.5 billion. I'm happy to report that we are now on track to beat our 2025 cost plan by over $1 billion on a GAAP basis and by $900 million on a cash cost basis, both at the midpoint of our projections.

During our previous 2Q call, we have lowered our GAAP and cash cost by $400 million each, with GAAP costs lowered from $6.4 billion to $6 billion, and cash costs lowered from $5.5 billion to $5.1 billion. Today, we are further lowering our 2025 expense guidance due to additional progress across the company to drive efficiency gains and continued investment prioritization.

Our GAAP operating expense guidance is being reduced by another $700 million from $6 billion to $5.3 billion at the midpoint. This reduction is $500 million of cash costs, plus $200 million of non-cash reductions in stock-based compensation and depreciation.

The $700 million GAAP reduction from prior guidance is split evenly between cost of sales and R&D. We are lowering our cost of sales forecast by $300 million to $400 million from $1.2 billion to a range of $0.8 billion to $0.9 billion, which reflects an acceleration of the efficiency programs we are targeting as part of our multiyear cost-out plan. We are also lowering our R&D expense range to $3.3 billion to $3.4 billion and approximately $350 million improvement due to continued investment prioritization and efficiency gains in the execution of our clinical trials.

In just two years, we expect to reduce our cash cost by approximately 50% from nearly $9 billion in 2023 and to $4.6 billion in 2025. We are now ahead of our plans, and we'll update improvements to our 2026 and 2027 targets at our upcoming Analyst Day on November 20.

Importantly, we continue to target cash breakeven in 2028. I would like to take this moment to thank all my Moderna colleagues for their hard work and commitment to improve the financial profile of our company. Moving to Slide 10. I will share our updated 2025 financial framework.

For total revenue, as I mentioned in my earlier remarks, we are narrowing our range to $1.6 billion to $2 billion from our previous guidance of $1.5 billion to $2.2 billion. For cost of sales, our updated guidance is $0.8 billion to $0.9 billion, an improvement from our previous guidance of $1.2 billion. This updated range assumes a higher cost of sales in 4Q versus 3Q, which factors in similar sales volume and higher unutilized manufacturing charges. Newly introduced tariffs are not expected to have a material impact on our business, but we continue to monitor changes to global tariffs.

Our revised R&D range of $3.3 billion to $3.4 billion, projects an increase in 4Q spend due to the seasonality of vaccine trial spend as well as studies in support of regulatory approvals. SG&A expenses are expected to be $1.1 billion. Similar to last year, we expect SG&A expenses in the fourth quarter to increase primarily due to commercial related activity. We expect taxes to be negligible in 2025. We expect our capital expenditures are also supposed to be approximately $300 million.

We are increasing our year-end cash guidance to $6.5 billion to $7 billion, an increase of $0.5 billion to $1 billion from our prior guidance of approximately $6 billion. This increase is projected to increase year-end cash due to the reduction in our operating expense for the year.

In summary, we have made strong financial progress against our 2025 financial objectives. We have tightened our sales range because of increased visibility into our seasonal sales. And we have lowered our 2025 cash cost estimate by $900 million from $5.5 billion to $4.6 billion, resulting in a higher projected year-end cash balance of $6.5 billion to $7 billion.

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

Stephen Hoge - *Moderna Inc - President*

Thank you, Jamey, and good morning or good afternoon, everyone. Today, I'll review our current commercial positioning in the US as well as our progress across our pipeline. As you know, COVID vaccine sales still represent the vast majority of our revenues. And as Jamey pointed out earlier, the US is our largest market in 2025.

Slide 12 reviews the US COVID vaccination market during the fall of '24 and the cumulative vaccinations to date for the retail channel for the fall of '25 as reported by IQVIA. As a reminder, the retail channel represented 72% of the total vaccinations in the fall of 2024. We expect this segment will represent a similar proportion of the market in 2025.

As Jamey noted earlier, our US revenue guidance is $1.0 billion to $1.3 billion. This range is based on our pre-season expectation for a 20% to 40% decline from fall 2024 retail vaccinations of approximately $26 million. As of October 24, of this year, cumulative retail vaccinations were $13.2 million, down approximately 30% year over year and well within the 20% to 40% decline we had assumed in our 2025 U.S. revenue outlook. Moving to Slide 13.

Our COVID retail market share is 42%, up 2 percentage points from last year. We are most pleased by the strong market uptake for mNEXSPIKE even given a midyear launch. mNEXSPIKE now makes up 55% of our COVID vaccination volume.

Slide 14 is a summary of our prioritized pipeline. This pipeline now consists of 3 approved products, 2 programs with positive Phase III results and 5 more candidates in clinical studies with registrational potential. Moving to Slide 15, which outlines the latest developments in our late-stage respiratory portfolio, I think to start with our COVID vaccines.

As mentioned earlier, Spikevax updated 2025, 2026 formula is now approved in 40 countries. For mNEXSPIKE, we received approval for the '25, '26 formula in the US And we are also approved in Canada. We have also applied for approval in Europe, Australia, Taiwan and Japan and would expect to launch in those countries in the '26, '27 seasons.

For mRESVIA, our RSV vaccine, it has been approved for adult age 60 and older in 40 countries and also approved for high-risk adults aged 18 to 59 in 31 of those 40 countries. We recently presented multiple data sets from the mRESVIA clinical program at ID Week.

For our flu vaccine candidate, mRNA-1010, we expect to complete regulatory submissions for approval in the United States, Canada, Australia and Europe by January 2026. The positive results from our Phase III vaccine efficacy trial were presented at both ID Week and the European Scientific Working Group on influenza or as we, this past month. Moving on to mRNA-1083, our combination flu covid vaccine candidate.

Our filing for approval is under review with the European Medicines Agency. And we expect to refile with Health Canada by the end of 2025. In the US, we are awaiting further guidance from the FDA on our plans to refile. We presented Phase III immunogenicity subanalysis for our flu COVID combination program at (inaudible). Now turning to our non-respiratory vaccine and rare disease portfolios.

Our ongoing Phase III norovirus study has not yet accrued sufficient cases needed to conduct the interim analysis after the first season. And as a result, we will proceed to enroll a second Northern Hemisphere season this winter. As before, the timing of the Phase III readout will be dependent upon accruing sufficient cases to trigger the interim analysis.

For mRNA-1647, as we announced in late October, we did not meet the primary endpoint for prevention of infection in our Phase III CMV efficacy study. We are discontinuing development in congenital CMV. However, we will continue to evaluate mRNA-1647 in an ongoing Phase II trial in patients who are undergoing bone marrow transplantation.

In rare diseases, I'm happy to announce that we have reached target enrollment of the registrational study for our propionic acidemia or PA program. We also had the opportunity to present data from our ongoing Phase I/II study at the International Congress of Inborn Errors of Metabolism Medical Meeting during the quarter. For methamolonic acidemia, or MMA, we presented interim data from the Phase I/II trial at that same meeting, and we expect our MMA registrational trial to start in 2026. Turning now to our oncology portfolio.

We continue to make significant progress in advancing our programs. For (inaudible), which is partnered with Merck, we have several late-stage studies underway. Our Phase III trial in adjuvant melanoma is fully enrolled and accruing events towards its interim analysis. Our Phase II adjuvant renal cell carcinoma trial is also fully enrolled. And as we have disclosed previously, we have 2 Phase III studies in non-small cell lung cancer and multiple randomized Phase II studies, including a Phase II study in high-risk muscle-invasive bladder cancer and a Phase II study in high-risk non-muscle invasive bladder cancer, all of which are still enrolling.

We've also expanded our (inaudible) program into the metastatic study with a Phase II study in first-line metastatic melanoma and a recently opened Phase II study in first-line metastatic squamous non-smelter cell lung cancer. Both these studies are randomized trials. Neoantigen from neoantigen analysis from our Phase II adjuvant melanoma trial was presented at the Society for Melanoma Research meeting in October.

Now moving to mRNA-4359, which is enrolling a Phase II study in first-line metastatic melanoma and first-line metastatic non-small cell lung cancer patients. The decision to proceed to that phase into those Phase II was based on encouraging Phase Ib data, some of which was presented at the recent ESMO Medical Congress.

In early-stage oncology, we are dosing patients in a Phase I trial for our cancer antigen therapy program, mRNA-4106. For our T-cell engager program, mRNA-2808, I'm happy to announce that the first patient was dosed in the Phase I trial during the quarter.

Finally, the IND for our cell therapy enhancer, mRNA-4203, is open, and we look forward to enrolling and dosing the first patient in that study. We're pleased by the growth and breadth of our clinical stage oncology pipeline and the continued strong momentum of the multiple Phase III and randomized Phase II trials within our (inaudible) clinical trial program conducted in partnership with Merck.

With that, I will hand the call over to Stephane.

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

Thank you, Stephen and Jamey. Looking at the three value drivers of our business: commercial, pipeline and financial. Commercially, we are seeing the benefit from market share gains of mNEXSPIKE, which we believe will continue in 2026 and beyond. Next year, our commercial business will benefit from the full year contribution from our strategic partnership in Canada, UK and Australia.

From a pipeline standpoint, we look forward to potential approvals of our combination of flu plus COVID vaccine in Europe. The file is currently being reviewed and in Canada, where we expect to revise soon. In the US, we look forward to refiling further guidance from the FDA.

Later this year, we filed our seasonal pro vaccine mRNA-1010 for approval in the US, Canada, Australia and the EU. We also expect to see two critical milestones from our (inaudible) program. First, the five-year follow-up data from our Phase II adjuvant melanoma study; and second, the efficacy data from our Phase III adjuvant animal study. We look forward to the Phase II data from our cancer (inaudible), we have to look forward to a Phase III efficacy data from norovirus vaccine and the restriction an efficacy study data for PA program propylitic acidemia in rare disease.

We have exercised strong financial disciplines so far this year. We have ahead of our initial 2025 cash cost production by $900 million. We will continue to improve our cost structure and drive productivity.

For (inaudible) cash balance projection, we have increased our year-end projection to a range from $6.5 billion to $7 billion, up $500 million to $1 billion from our prior guidance of around $6 billion. We know that a higher cash balance to exit 2025 and a much ecostructure when we enter 2025 is the right strategy as we transition from a single pandemic product company to a large, diversified portfolio of commercial products in seasonal vaccines, oncology medicines and rare disease medicines.

In closing, I want to recognize the entire Moderna team for their net less dedication to our mission. For our progress, scientific, clinical, commercial and operational is focused on our mission, delivering the greatest possible impact to people for mRNA medicines.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Salveen Richter, Goldman Sachs.

Salveen Richter - *Goldman Sachs Group Inc - Analyst*

Good morning. Thanks for taking my questions. As we look to the expense management on the forward here, can you help us understand what's being deprioritized or change to allow for these changes? And then secondly, in accordance with kind of Roivant and the IP dynamics that are playing out here, can you just frame your strategy here on the Board as we look into 2026? Thank you.

James Mock - *Moderna Inc - Chief Financial Officer*

Sure. Thanks for the questions. I'll take the first one. So it depends on your reference point in terms of what you talk about from a cost-out perspective over the last few years, as I mentioned, we're down 50% from a cash cost basis. But a more recent in our recent $500 million to $700 million reduction, that split evenly across R&D and cost of sales.

So cost of sales is purely driving efficiencies, everything that the teams are hard at work and have been hard at work doing. They're just accelerating and getting it done faster. So that's unutilized manufacturing capacity that is all the waste that we saw in materials. They're doing a great job reducing that, driving productivity within the labor force. So that's not really a deprioritized investment.

On R&D, it's a bit of both. It is -- the execution of our clinical trials has been much more efficient. We've talked in the past about the fact that we were operating for speed. And this time, we are operating for cost as well in efficiency. So a lot of this is just the execution of our trials. But we are making decisions here and there to not continue to advance to Phase II or Phase III or even out of Phase I here and there.

Broadly, we're taking down our just big picture story from the last couple of years. Our large Phase III vaccine trials are really running down and winding down, including CMV recently and flu combination vaccine. And after that, we are moving into oncology, which is a different amount of patients that are under those trials.

So there is some prioritization in there, as we've always said, but a lot of it is also execution. But we still have prioritized our pipeline. So we are excited about the 9 or 10 late-stage programs that we have that Stephen highlighted in his prepared remarks, and we look forward to continuing to take out additional costs, and we do see that coming down over the coming years, and we'll update you more at the Analyst Day.

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

And good morning, Salveen. On (inaudible), the trial in the US is scheduled for March 9, 2026. We remain confident in the groundbreaking technology with Pioneer, including our lipid-nanoparticle delivery system were vigorously defending the case and responding to new filings outside the US. We believe that our technology does not infringe any valid patents asserted by (inaudible).

Operator

Gena Wang, Barclays.

Gena Wang - *Barclays Services Corp - Analyst*

Thank you for taking my questions. Maybe two very quick questions. First one is regarding the US COVID revenue, $781 million, that I assume majority of this basically is the inventory build-up delivery to the pharmacists. So maybe how often do you track pharmacies to maintain their inventory? And what are additional color you can share regarding your estimate of the revenue for the remaining of this year?

And then second question is regarding the CMS -- sorry, CMV vaccine. So what is the learning there? Why immunogenicity data did not translate to clinical benefit?

James Mock - *Moderna Inc - Chief Financial Officer*

Okay. So thanks, Gena. Good to hear from you. I'll take the US sales. So ultimately, the end measure is vaccinations in the US that shots and arms. And so in the third quarter, yes, we ship a lot of our product into wholesalers and then they take it down to our pharmacists, whether that's a retail pharmacy or an IDN network, a doctor, a physician's office. And so we track that almost daily.

And really, what we put what Stephen shared with you on the screen is that's why we show shots and arms. We believe that's the ultimate measure. And if you look at season to date through October 24, shots and arms are down in the US, 30%. There's a lot of reasons for that, some of which we anticipated.

And if I take this back to our guidance, -- when we originally guided at the beginning of the year, we said $1.5 billion in the US sales, $1 billion to $1.5 billion. The $1.5 billion was essentially flat year-over-year for all aspects, whether it's market share, competitive dynamics, vaccination rates, et cetera, excluding a onetime item from the prior year. And the $1 billion, as I said, is down 33%. So we obviously anticipated that the vaccination rate, which is the largest variable here, could go down. And so now we've seen that go down and we've reduced our range. So we said that we believe vaccination rates will now be down 20% to 40%.

And we are in the heart of the vaccination season. We're probably half to 2/3 of the way through. So we have good visibility to this. We are measuring shots in arms. We talked about our share as well. And we also look at every single day and every single week is there more pull down? Is it more pull down to the physicians? Is it more pull down to retail -- are there more shipments even in the fourth quarter. So -- and we feel very comfortable with our range now of $1 billion to $1.3 billion, but we do not see vaccination rates in the US getting back to flat, which is the change from the high end, from going from $1.5 billion to $1.3 billion.

Stephen Hoge - *Moderna Inc - President*

Great. And Gena, I'll take the CMV question. So first, we really only have, at this point, the top line data from that trial. And over the coming weeks and months, we will get a tremendous amount of more information, including detailed information on a bunch of other immunogenicity and potentially even correlate production and have the ability to generate hypotheses on what maybe didn't work.

What I can say at this point is, as you know, going into the trial, we and the field had high hopes that a Pentamer neutralizing antibody response, which had not been a part -- a strong (inaudible) response, which had not been a part of previous attentive vaccine was going to be the missing piece for being able to prevent infection with a CMV vaccine. Prevention of infection with the herpes virus or in CMV was an incredibly high bar. It was a difficult bar to go after. But ultimately, the only one we thought that we could test that had a chance at meeting our target product profile for prevention of congenital CMV.

So I guess what we can say at this point until we get that additional data is it looks like and Pentamer neutralizing antibodies weren't the missing piece and that it wasn't sufficient by itself to drive a dramatic improvement in the prevention of infection with CMV. Now we'll dig into the data as we get it over the coming months, obviously, look forward to publishing and sharing it at medical conferences. And hopefully, the entire field can learn where vaccine development in CMV might need to go next. But ultimately, Pentamer wasn't enough.

Operator

Cory Kasimov, Evercore.

Cory Kasimov - *Evercore Inc - Analyst*

Good morning, guys. Thanks for taking the questions. I shift gears over to the pipeline. I want to ask about your norovirus program. Are you surprised at all by the low case accruals here? Or is this kind of anticipated? And do you believe this offers any sort of reflection on the commercial opportunity or potential demand for the product should it be approved? Thank you.

Unidentified Company Representative

Thanks for the question, Cory. So predicting epidemiology and norovirus is still an early space. And so we had always designed the study as a potential 2-season study. In fact, we're we'd always expected that it was possibly going to be necessary, that happens in flu vaccines, that has happened in other respiratory vaccines, other vaccines based on case accrual, happened to us here.

I think we believe we're getting better at predicting where that epidemiology will be, where we cite the trials and ultimately being able to recruit cases that are matched to the vaccine come position. And I think we are hopeful that with this additional second season, which was always a possibility that we'll be able to show -- or accrue enough cases to conduct that and ultimately demonstrate the efficacy of the vaccine.

The impact on commercial target product profile we forward, I would say we don't believe that there's been a change to that. At the end of the day, what matters here is hopefully a highly effective vaccine against preventing norovirus. It is a well-established burden of disease globally. And we do believe that the health economic benefit of prevention of severe to moderate infections with norovirus will be clear, particularly those that are at highest risk, including those that live in long-term care facilities or for other occupational reasons might be at risk. So we still feel strongly about that target product profile and think that the epidemiology challenges of the last season will be addressable with the second season of enrollment.

Operator

Luca Issi, RBC

Luca Issi - *RBC Capital Markets Inc - Analyst*

Great. Thanks so much for taking my questions. Congrats on the progress.

Maybe, Jamey, can you just talk about what gives you confidence that you can reiterate your cash breakeven guide for 2028? I appreciate you're making some fantastic progress in terms of like managing the OpEx and the CapEx, but still the cash cost at the midpoint this year is $4.6 billion. So I think in order to break even in 2028, you really need your top line to reinflect quite materially from here. So can you just talk about that?

I mean, it looks like COVID is still declining. RSV, maybe it's one and done for now. CMV did not make it. IMP initially, it's going to be just for adjuvant melanoma. So what are the near-term product that you think can really inflect the top line in the foreseeable future?

And then maybe second, Stephane, quickly. I think a few media outlets have reported in Moderna is working on potential large deals with pharma. So wondering if you can comment on that. And then maybe bigger picture, what's your latest thinking on (inaudible) these days. Thanks so much.

James Mock - *Moderna Inc - Chief Financial Officer*

Thanks, Luca. There's a lot in there. And I -- we recognize it's on everybody's mind, and we're going to lay this out at the Analyst Day, just so you know. So -- but I'll mention a couple of things here.

When we say and we all commit to breaking even, it is both a mix to your point of revenue growth and cost reduction. And so on the cost reduction side, as I mentioned earlier, to Salveen's question, we see ample opportunity. And I mentioned that we will update our 2026 and 2027 framework at the Analyst Day, but there's still plenty to do on that front.

On the revenue side, we have -- we see a lot through geographic expansion through our strategic partnerships that I mentioned in my prepared remarks, through new product introductions. We'll get them to lay that out in a more fulsome way at Analyst Day, but we remain committed. But yes, it is a mix of both the revenue side growing as well as the cost side reducing, and we still feel confident in our plan.

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

Thank you, Jamey. And on the deal side, as we spoke about in several of our last calls, we really want to get products like the latent vaccine like EBV, for example, to patients. As we've said, part of our privatization of our portfolio, we do not want to fund a Phase III by ourselves. And so we are talking to our companies. We are talking to financial sponsors. As you know, we have a partnership with Blackstone that we did on flu, mRNA-1010. So those discussions are ongoing. And when we have something to communicate, we will.

Operator

Tyler Van Buren, TD Cowen.

Unidentified Participant

Thanks for taking my question. This is Greg on for Tyler. It looks like mNEXSPIKE is already taking the slight majority of your COVID vaccinations over Spikevax. So how do you expect the split between these 2 vaccines to continue to evolve? And I'd also be interested to hear what feedback you're hearing from pharmacists and other clinicians about mNEXSPIKE so far. Thank you.

Stephen Hoge - *Moderna Inc - President*

Thanks for the questions. So we're obviously really pleased with that launch. It has become our leading product in the overall COVID franchise. And that's been, frankly, exceeded our expectations in a positive way. It really speaks to the profile. We think the clinical data as well as the overall sort of momentum in the market towards higher risk populations. Some of that is a result of changes in recommendation in this country, towards in the United States towards higher risk individuals and those over the age of 65.

We're continuing to build out that medical story, and the data has been shared obviously at ACIP, but in medical meetings. And we hope to continue to build momentum behind the mNEXSPIKE brand as our leading product in the franchise.

Now Spikevax will always have a place. And as you know, Spikevax is the only approved product in pediatrics down to six months to four-year olds. And that is an important population, particularly for those with high risk factors, those with lung disease or those with underlying comorbidities, even in the young population. So we will always expect some portion to be at Spikevax, but over time, we would hope that the older adults and higher risk populations might migrate to mNEXSPIKE. That's consistent with the feedback we've been getting.

And in fact, if you look at many of our large customers, both health systems and pharmacies, that is how they are thinking about the products and using them. We'll be working with governments around the world as we move to not launch mNEXSPIKE -- sorry, as we move to launch mNEXSPIKE outside of the US for the next season, and we hope to continue to see growth in that brand as a part of our overall franchise.

But as I said, we will always have both. I don't have specific guidance on the split because at the end of the day, this is a decision made by health care providers and customers about what's the most appropriate choice for their patients.

Operator

Jessica Fye, JPMorgan.

Unidentified Participant

Good morning. Thanks for taking my question. (inaudible) for Jessica. How is the US COVID vaccine, demand tracking disease relative to your projections? And what about the ex-US season? And also, can you orient us around the potential annual revenue contribution tied to the manufacturing sites in the UK, Canada and Australia? Thank you.

Unidentified Company Representative

Yes. So yeah, I'll break it down, the US, so US and then the manufacturing contribution. So -- it's track. I think I mentioned this a little bit already. So our revised guidance is $1 billion to $1.3 billion in the US. We anticipate the vaccination rates are -- could be in the range of down 20% to down 40%. And -- that's not too different than what we thought at the outset of the year that it could be flat to down. We definitely incorporated a scenario where vaccination rates going to be down, but we feel good about it. We are mostly we're halfway through the season and feel good about and have confidence in our U.S. range.

Outside the United States, we actually raised the bottom end of our revenue guidance. So we used to be $0.5 billion to $700 billion, now it's $600 million to $700 million. That's due to -- everything is now contracted. A lot of it has been delivered. And as we look to the last couple of months of this year, what's really coming down with the only variables left or delivery timing, whether some of these falls into the first quarter of 2026 or in remains in 4Q '25. And then there are a couple of markets that are predicated upon vaccination rate. So the demand is still tied vaccination rates. So we feel very comfortable with our range outside the United States as well.

Then in terms of the strategic partnerships, if you remember in, I think, the second quarter, we said that the deliveries for our UK strategic partnership has already shifted outside the year, which was the reason we dropped the high end from $2.5 billion at that time to $2.2 billion. So we do not expect any revenue inside this year. That will be pure growth in the year 2026.

I mentioned in my prepared remarks that half of our international revenue was in Canada in the third quarter. So Canada is up and running. We believe Australia will be up and running from a revenue perspective, that is in the fourth quarter, and then the UK in the first quarter of next year. So we feel good heading into next year that we should be able to see some revenue growth from our strategic partnerships.

Operator

Geoffrey Meacham, Citigroup.

Geoffrey Meacham - *Citibank Cameroon SA - Analyst*

Hey, guys. Thanks so much for the question. I have two for you. So the first one on the cost reduction and just looking at the 2028 breakeven target, I was curious if your pipeline evaluation process has evolved, just to look at maximizing ROI on your R&D investments.

And then on the rare disease platform, what's the capacity in this TA to add more programs? It does seem like it could be quicker to get the proof-of-concept data, but I just maybe wanted to compare that to oncology and how you guys are thinking about it. Thank you.

Stephen Hoge - *Moderna Inc - President*

Thanks for both those questions. So first on R&D, I think it was a couple of years ago and reiterated last year that we said as far as large Phase III programs in our infectious disease pipeline, that we would defer further Phase III investments until we crossed breakeven -- cash breakeven in 2028. And then as a result of that, there would be this substantial downshifting in our R&D expenditures over last year and this year and the next year ahead as the large Phase IIIs for flu, (inaudible) COVID, for CMV and even norovirus runoff. And so we've maintained that position all the way through how we've been constructing our pipeline, which I would say is not necessarily ROI maximizing. It is cash and investment optimizing.

We do believe we have several compelling Phase II programs. EBV is one example of a vaccine against (inaudible) and perhaps multiple sclerosis, but one that we are not moving forward with in terms of investment. I believe that ROI is attractive and positive we do, but we will wait to make investments until we've shown we can break even based on the current products. And so that's the way our portfolio has been evolving from a construction perspective.

Now there are instances and for instance, in our oncology space, where we do see an opportunity to make cash investments within our prior guidance, whether that's with the Intisar in program or with 435 that we think are -- have a very attractive ROI and again, can fit within our breakeven guidance for '28. And so those are instances of where we will continue to move forward.

And maybe that's a natural segue to the last part of your question, which is that is also true, to some extent, in the rare disease space. We have the two programs, PA and MMA, that are moving towards or in the case of PA fully enrolled in their potential registrational studies. And it is a platform where we do believe we can do much more.

There is a very large number of diseases for which we think the technology can work. But again, we want to demonstrate discipline. And so we are not prioritizing making further investments in the rare disease space. until we have PA and MMA through those registrational studies and ideally until we also achieve our breakeven targets for '28. It is a lower cash investment to move those programs forward.

And so as you alluded to, it might be a place that naturally as we get more comfortable over the next year or two that we start moving perhaps a third or a fourth program through, but that will have to be balanced against further investments in oncology like the (inaudible) programs or potentially the re-initiation of pivotal investments in our infectious disease portfolio. And at this point, we'll make those decisions in the future and haven't got a strategic view one way or the other right now.

Operator

Courtney Breen, Bernstein.

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

Hey, guys. Thanks so much for taking my questions. Just wanted to probe a little bit more on the R&D cut. Perhaps kind of and contrasted Salveen's question, perhaps a little bit more forward-looking. As you think about kind of the efficiencies that you've garnered and the new approach, are there more cuts that you can make going forward to that R&D plan? Or would that require actually stopping of programs or changing kind of your prioritized list of assets that you have in the pipe? Thank you so much.

Stephen Hoge - *Moderna Inc - President*

Thank you for the question. So we do expect further reductions in costs. We've previously communicated how we were moving towards breakeven. And so today's cash costs for 2025, while they are better than our guidance, they are not done. And we expect further reductions in our GAAP cost for R&D over the coming year and two purely based on the sunsetting of our existing prioritized investments.

And so we believe that those reductions will happen without further stops. And we will continue to do investment in the early-stage space as well, which as you know, is a less cash-intensive, capital-intensive area. So at this point, we believe we can continue to drive efficiencies and further cost reductions in our R&D investment in the coming years simply by completing the work that we had started several years ago in our infection disease vaccines portfolio.

Operator

Myles Minter, William Blair.

Unidentified Participant

This is John on for Myles. Thanks so much for taking my question. So maybe a follow-up to an earlier question on the CMV program. I know that you're still going through the data, but I was wondering if you could speak to any read-through from the CMV trial missing to any of your other latent vaccine studies or if you view the CMV miss as an isolated event?

Stephen Hoge - *Moderna Inc - President*

Thanks for the question. So CMV was unique in our pipeline in that it is the only pivotal study, a Phase III study that we were running against a latent virus and the only one that was going after a prevention of infection. So we do believe that prevention of infection was unfortunately the only way to try and demonstrate a potential for the vaccine against congenital CMV, but it was by far the highest bar.

Vaccines generally don't prevent infections, they prevent diseases from the viruses. And even in the case of CMV, we still believe that there's an opportunity for mRNA-1647 to have an impact in patients undergoing bone marrow transplant, where they are already infected, but they see a reactivation of their CMV that can have serious potential morbidity and mortality. And for that reason, we think there's an opportunity for a vaccine to help control that reactivation even a vaccine against CMV.

So I guess I would say we don't have other programs in our late stage or prioritized pipeline that have a similar read-through or read-through from the CMV results because we are not trying to prevent infection with any of them. We're trying to prevent diseases. And even in the case of CMV, we see a potential opportunity in an indication like bone marrow transplant, CMV reactivation, where, again, target product profile is going against prevention of a disease prevention of infection.

Operator

(Operator Instructions)

I'm not showing any further questions at this time. I'd like to turn the call back over to Stephane for any further remarks.

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

Well, thank you, everybody, for joining today. We look forward to talking to many of you in the coming days and weeks. And we look forward to seeing many of you here on campus on November 20 for Investor Day. Have a great day. Thank you.

Operator

Ladies and gentlemen, this does conclude today's presentation. We thank you for your participation. You may now disconnect, and have a wonderful day.