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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 second quarter 2026 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 - 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 second quarter 2026 financial results and business update. You can access the press release issued this morning as well as the slides that we'll be reviewing by going to the Investors section of our website. On today's call are Stephane Bancel, our Chief Executive Officer; Stephen Hoge, our President; Jamey Mock, our Chief Financial Officer; and David Berman, our Chief Development 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. After my review of the second quarter, Jamey will present our financial results and outlook, followed by Stephen with recent business updates. And David will review our clinical progress in oncology and rare diseases.

And then I will close by discussing our key value drivers. As you know, the second quarter is always light for seasonal vaccines. We generated revenue of $0.1 billion, which exceeded the top of our range. Our focus on financial discipline continued. We reduced cash cost by 10% in Q2 compared to the second quarter of 2025.

We reported a net loss of $0.8 billion. We ended the quarter with $6.9 billion in cash and investments, maintaining a strong balance sheet while continuing to invest in our pipeline. Overall, I am pleased with our continued execution across the business. This team has done a great job to get us ready for the '26, '27 vaccination season, and our pipeline is progressing well. During the quarter, we delivered several important updates across our pipeline.

In our respiratory portfolio, our seasonal flu vaccine, mRNA-1010, received a positive recommendation from the US VRBPAC. This represents another important milestone ahead of our August 5 PDUFA date and brings us one step closer to potentially making our flu vaccine available to patients. For our norovirus vaccine, mRNA-1403, following an interim analysis, we are preparing to enroll an additional cohort in its Phase III trial. In oncology, we are very pleased to present the 5-year Phase II update of intismeran autogene in combination with KEYTRUDA in adjuvant melanoma at ASCO 2026, highlighting the continued durability of the clinical benefit observed of this program.

We also presented important translational data that provides additional confidence in the mechanism of action of our individualized neoantigen therapy. And finally, we're excited to announce that dosing has begun in 2 cancer antigen therapy programs. The Phase I/II study of mRNA-4194 in Lynch syndrome and the Phase I study of mRNA-4200 in solid tumors. Beyond our pipeline, we also had several notable corporate achievements during the quarter. We are pleased to expand our partnership with CEPI to explore the development of an Ebola vaccine, reinforcing our long-standing commitment to global health security and pandemic preparedness.

We were also honored to be named the World's Most Impactful Company by Time Magazine, recognizing our pioneering work in mRNA science. This recognition reflects both the global impact we made during the pandemic and our continued effort to advance a broad pipeline of innovative medicine and expand access to mRNA technology worldwide. Turning now to our leadership team. I'd like to highlight 2 important appointments we announced this quarter. As we continue to strengthen Moderna for the next phase of growth, I'm very pleased to welcome Ester Banque as our new Chief Commercial Officer.

Ester joined us with more than 30 years of commercial leadership experience and an outstanding track record of leading high-performing organization across the health care industry. More recently, she led US operation at Zoetis and before that, held several commercial leadership role at BMS and Novartis, where she helped bring important medicines to patients around the world. Ester now leads our global commercial organization as we prepare for multiple launches and continue expanding into new markets. We are delighted to have Esther join Moderna and have been enjoying working closely with her.

I'm also pleased to welcome Michael McDonald to Moderna's Board of Directors. Michael is familiar to many of you as most recently, he served as Executive Vice President and Chief Financial Officer of Biogen. Michael brings more than two decades of public company CFO experience and deep expertise across finance, capital markets, Investor Relations and corporate governance. His experience across the life science and technology sectors will be a valuable addition to our Board as we continue to execute our strategy and create long-term value. We are delighted to welcome Michael to Moderna's Board.

With that, I will now turn to Jamey.

James Mock - *Moderna Inc - Chief Financial Officer*

Thanks, Stephane, and hello, everyone. Today, I'll start with our second quarter financial results and then review our updated financial framework for 2026. Let me start with our commercial performance. For the second quarter, total revenue was $145 million, above the guidance range we provided on the first quarter call. Our geographic mix for the quarter was 60% US and 40% international. For the first half of the year, total revenue was $0.5 billion with 31% from the US and 69% from international markets. Our long-term strategic partnerships drove the strong international contribution during the first half. Overall, we are pleased with our first half performance and are reiterating our expectation for revenue growth of up to 10% in 2026.

We continue to expect a roughly 50-50 split between US and international revenue for the full year, and we expect third quarter revenue will represent approximately 55% of our second half revenue. Now let me turn to our second quarter financial performance on Slide 10. As I just mentioned, revenue was $145 million in the quarter, up 2% from the prior year. Cost of sales for the quarter was $93 million, a 22% decrease compared to the prior year, primarily driven by lower unutilized manufacturing capacity costs as we continue to improve our manufacturing efficiency.

R&D expenses for the quarter were $651 million, a 7% decrease compared to last year. The decline was driven by lower clinical development costs following the wind down of several late-stage programs. SG&A expenses for the quarter were $216 million, down 6% from last year, reflecting continued cost discipline across the organization. Our income tax provision was immaterial in both periods as we continue to maintain a global valuation allowance, which limits our ability to recognize tax benefits from losses. Net loss for the quarter was $782 million, improving by $43 million or 5% compared to last year.

Loss per share was $1.97, and for the quarter compared to $2.13 last year. We ended the quarter with cash and investments of $6.9 billion compared to $7.5 billion at the end of the first quarter. The decrease primarily reflected cash used to fund operations as we continue to invest in R&D and advance our pipeline. In July, we paid $950 million related to the litigation settlement announced earlier this year, which will be reflected in our third quarter cash balance. Now let's turn to our financial framework for 2026.

We still expect total revenue to grow up to 10% in 2026 with the geographic mix and quarterly phasing I previously mentioned. Our 2026 revenue guidance factors in potential future declines in COVID vaccination rates and continues to assume no revenue from mFlusiva and mCombriax. We are lowering our cost of sales projection by $0.1 billion to $1.7 billion, reflecting additional manufacturing efficiency gains. The $1.7 billion estimate includes $0.9 billion of expense related to the previously announced litigation settlement charge. We are also lowering our R&D expense estimate by $0.1 billion to $2.9 billion due to operational efficiencies and SG&A expenses are still expected to be approximately $1 billion, flat versus the prior year.

Similar to 2025, our commercial spend will be more heavily weighted to the second half of the year due to the seasonality of our business. In aggregate, excluding the $0.9 billion litigation charge, we are expecting total GAAP operating expenses of $4.7 billion and $4 billion of cash costs which excludes stock-based compensation, depreciation and amortization, each reflect a $0.2 billion improvement compared to our previous guidance. We expect taxes to be negligible in 2026. Capital expenditures are still projected to be between $0.2 billion and $0.3 billion. Cash and investments are now projected to be between $4.7 billion and $5.2 billion at the end of 2026 which reflect the improvement in our cash cost guidance. As a reminder, our cash guidance does not assume any additional drawdown from our remaining $0.9 billion undrawn credit facility.

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 take you through our recent business updates. Slide 13 outlines our multiyear revenue growth strategy, anchored in geographic expansion and portfolio expansion from the continued advancement of our product pipeline. For 2026, we continue to expect revenue growth of up to 10%, driven by our long-term strategic partnerships in the United Kingdom, Canada and Australia and supported by the continued growth of mNEXSPIKE. Looking across the 3-year horizon, we are

building toward a broader and more diversified portfolio, including flu, our combination flu/COVID vaccine and norovirus as well as late-stage programs in oncology and rare disease, while continuing to expand our global commercial footprint.

We're making tangible progress against this strategy, and mNEXSPIKE is now approved in Japan and Taiwan. Our flu program received a unanimous recommendation from the VRBPAC FDA Advisory Committee, and we signed a joint procurement contract with the European Commission for up to 24 million doses of mRESVIA across 6 countries. We also received approval for mRESVIA in Mexico and a label expansion for the product in Australia. In Latin America, we advanced our strategic partnership in Brazil by signing an agreement with a local manufacturer to support our multiyear COVID vaccine supply agreement with the government. Finally, as our commercial portfolio expands, emerging real-world evidence strengthens the support for our respiratory portfolio.

Slide 14 highlights our approved infectious disease portfolio and several recent updates across the products. Starting with COVID, health authorities in the United States and Europe have selected the XFG strain for the '26, '27 season, and we are updating both Spikevax and mNEXSPIKE to target this strain for the upcoming vaccination season. For Spikevax, we also recently published a real-world evidence study. A link to the study is included on this slide. And mNEXSPIKE is now approved in the United States, Europe, Canada, Australia and as mentioned earlier, now in Japan and Taiwan.

Additional filings are planned for the second half of 2026. We also published a real-world evidence study evaluating the adjusted vaccine effectiveness against COVID-related hospitalization during the most recent 2025, 2026 season, which I will discuss in more detail shortly. Turning to mRESVIA, which is approved in 44 countries. Most recently, it was approved in Mexico for all adults aged 60 and older as well as high-risk adults age 18 to 59. We also received a label expansion in Australia to include high-risk adults aged 18 to 59.

In addition, a real-world evidence study evaluating vaccine effectiveness against hospitalization and associated RSV-related acute respiratory illness was published for mRESVIA. Finally, mCombriax is now approved in the European Union and is under review in Canada, Australia and most recently, Japan. In the United States, we are awaiting approval of our stand-alone flu vaccine before seeking further guidance from the FDA on next steps for refiling the combo here. Slide 15 highlights the emerging real-world evidence supporting mNEXSPIKE's clinical profile.

As a reminder, during its first season on the market in 2025, 2026, mNEXSPIKE captured approximately 24% of the total US retail covid vaccine market. Uptake was particularly strong among older adults with mNEXSPIKE accounting for approximately 34% of the retail market among individuals aged 65 and older. This market uptake was supported in part by the Phase III head-to-head data of mNEXSPIKE versus Spikevax. The subsequent real-world analysis evaluated adjusted vaccine effectiveness against hospitalization with documented COVID-19 during the 2025, 2026 season.

Among adults age 65 and older, vaccine effectiveness was approximately 59% for mNEXSPIKE compared with a matched unvaccinated cohort. Among adults age 75 and older, it was approximately 67%. These estimates were numerically higher than those observed for a competitor vaccine and separately matched analysis. While this real-world study was not designed as a head-to-head comparison, the numerical differences are encouraging, particularly when considered alongside the vaccine efficacy observed for mNEXSPIKE versus Spikevax in the Phase III head-to-head trial. Taken together, the strong initial market uptake and the emerging real world evidence highlight mNEXSPIKE's potential, particularly among older adults.

Turning now to our late-stage infectious disease pipeline. And starting with flu, we are grateful for the unanimous VRBPAC recommendation for mRNA-1010 and look forward to the potential for approval with the PDUFA date of August 5 in the United States. mRNA-1010 is also under review in the European Union, Canada and Australia. The efficacy and safety results from our Phase III study were recently published in the New England Journal of Medicine. A link to the publication is included at the bottom of the slide.

For our norovirus vaccine, mRNA-1403, the Phase III study did not meet the statistical criteria for early success at its interim analysis. The study remains blinded as we now prepare to enroll an additional fourth cohort. With that, I will now turn the call over to David, who will provide a more detailed update on our oncology and rare disease pipelines.

David Berman - *Moderna Inc - Chief Development Officer*

Thank you, Stephen. Before I begin the review of our oncology and rare disease pipeline, I want to take a moment to say how excited I am to be here. Before joining Moderna, I followed the company's oncology portfolio and Intismeran, in particular, very closely. The strength and potential of the pipeline were an important part of what attracted me to the Chief Development Officer role. Since joining the company and spending time with the teams, I have become even more impressed by the quality of the science, the depth of the programs and the opportunities ahead of us.

With that, let me take you through the progress we are making across our oncology and rare disease pipeline. Starting with Intismeran, our individualized cancer therapy developed in partnership with Merck, the program continues to advance across a broad portfolio of 9 Phase II and Phase III studies. In adjuvant melanoma, the Phase III study is fully enrolled and we look forward to the interim analysis in 2026. At ASCO, we presented the 5-year update from the Phase II study of Intismeran in combination with KEYTRUDA in the adjuvant melanoma setting as well as translational data demonstrating the induction of de novo neoantigen-specific T cells following treatment. A link to our ASCO investor event presentation is on the bottom of this slide.

Our Phase III development program also includes studies in adjuvant non-small cell lung cancer, including a Phase III study in patients without a pathologic complete response following neoadjuvant therapy as well as the recently initiated Stage I study evaluating Intismeran, both as monotherapy and in combination with KEYTRUDA. Across the Phase II portfolio, the adjuvant renal cell carcinoma and muscle invasive bladder cancer studies are fully enrolled and continue to accrue events. We are often asked when we expect these studies to read out. Because both studies are event driven, it is difficult to predict the timing with precision. The renal cell carcinoma study has been fully enrolled since the second quarter of 2025.

So it is possible that the threshold for the analysis could be reached this year. However, it is also possible that this occurs next year. It depends on the pace of event accrual. The muscle invasive bladder cancer study completed enrollment earlier this year, and we currently expect the readout to be more likely in 2027, again, subject to the timing of event accrual. Non-muscle invasive bladder cancer study continues to enroll.

As a reminder, this trial is evaluating both Intismeran with BCG in combination as well as Intismeran monotherapy. Beyond the late-stage portfolio, our Phase I studies in adjuvant pancreatic cancer and perioperative gastric cancer are also fully enrolled, and we look forward to sharing data from these programs as they mature. Taken together, the breadth and continued execution across the Intismeran program reflect our commitment to evaluating this therapy across multiple tumor types and stages of disease.

Outside of Intismeran, we continue to advance a broad portfolio of oncology programs across cancer antigen therapies, T-cell engagers and cell therapy enhancement. mRNA-4359 is in a Phase II program in first-line metastatic melanoma and second-line or later metastatic melanoma. It is also being evaluated in first-line metastatic non-small cell lung cancer. We are also advancing 2 additional cancer antigen therapies. mRNA-4106 and mRNA-4200 in a Phase I study in patients with advanced solid tumors. I'm pleased to report that dosing has now begun with mRNA-4200 alongside the ongoing evaluation of mRNA-4106. In addition, mRNA-4194 has entered clinical development with dosing now underway in a Phase I/II study in individuals with Lynch syndrome.

This program is designed to evaluate the potential of our technology in an earlier cancer interception setting. Our T cell engager, mRNA-2808 also continues to advance in a Phase I/II study in multiple myeloma with patients actively dosing. Finally, in collaboration with Immatics, dosing continues in the Phase I study of mRNA-4203 in combination with the anzu-cel therapy. These programs demonstrate the breadth of our oncology pipeline and the continued progress we are making across several distinct therapeutic approaches. Moving now to Slide 20.

In rare diseases, our propionic acidemia, or PA program is fully enrolled in its registrational study, and we expect data from the study in 2026. For our methylmalonic acidemia or MMA program, as mentioned last quarter, we have deferred our decision on a pivotal trial until the PA readouts. With this review, I will now hand it over to Stephane.

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

Thank you, David, Stephen and Jamey. Looking at the second half of the year. On the commercial and financial side, we remain on track for up to 10% revenue growth this year and also remain committed to improving our operational efficiency and achieving our new lowered cash cost guidance of approximately $4 billion. We also expect to build on last year's successful mNEXSPIKE launch and to continue expanding access to the COVID patients around the world. We look forward to approvals for mCombriax in Canada and Japan.

And following the positive recommendation from the US VRBPAC, we now look forward to the August 5 PDUFA date and potential approval of our seasonal flu vaccine in the US. We also anticipate approval for flu in Canada and Europe. From a pipeline perspective, oncology remains a key focus with important milestones ahead for Intismeran in multiple tumor types. As David said, in our registrational study in PA, we expect data this year.

We have a busy second half of the year ahead of us. Success will come from disciplined execution across our key priorities, and I'm confident in our team's ability to deliver. We will be happy to host you in Cambridge or online for Analyst Day on November 12. Finally, I would like to thank our employees around the world for their continued commitment to our mission and for everything they have accomplished this quarter. With that, 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*

Two questions for me. One is in the case that the Phase III Intismeran melanoma study passes the first interim and progresses to a second and/or final analysis, how should we interpret that in the context of powering and event accrual? And how detailed will your disclosure be? And the second question for me. If the trial is indeed positive here, how do we think about read-through to other tumor types like lung in the context of tumor mutational burden but also the fact that you're talking about different neoantigens that play the key role there as you think about the cassette.

David Berman - *Moderna Inc - Chief Development Officer*

A lot of questions in there. I think with regard to your first question, if the Phase III INT study in melanoma continues it continues. We haven't disclosed the statistical powering or the thresholds for early interim efficacy. So I think I won't really address any more about that. With regard to the press release, I think it's too early.

Let's see what the data is, and then we'll figure out what exactly the wording will be in the press release. I think with your other question, if Intismeran is positive, what's the read through, I think it's a very important question, one I've given a lot of thought to. I think there are several important things we need to see here. One is what is the degree of efficacy that we see. Number two, are we confident that the mechanism that we see can be validated.

And I think with regard to that, the data that we've shown at ASCO confirms that we do -- when we give the neoantigen vaccine, we do see neoantigen-specific T cells, and we know those T cells can kill the tumor. So I think that we have moved to other tumors where checkpoints do work, and we know that this mechanism that I just talked about is the mechanism by which other checkpoints do work. And so since checkpoints work in lung cancer, and bladder, I think that gives us increased reason to believe in bladder. I think the big question comes

out in tumors where checkpoints don't work and that's pancreatic cancer and to a lesser degree, gastric. So that's why we're conducting Phase II trials and Phase I expanded trials in those other tumors.

Stephen Hoge - *Moderna Inc - President*

And Salveen, maybe on your first question, just to fill in a little bit. As David said, we haven't disclosed the statistical analysis plan. But suffice it to say, it's an interim analysis, and there are still subsequent planned analyses. And ourselves with our partner, Merck designed the overall study to evaluate the full commercial profile of the product. And so we do think that there's a commercially valuable product that could emerge maybe only in the final analysis, but that wouldn't meet the criteria for early efficacy at the interim. And obviously, we'll move forward with the study accruing events to characterize that, but we do still see there is an opportunity there.

Operator

Tyler Van Buren, TD Cowen.

Tyler Van Buren - *Cowen and Company LLC - Analyst*

Another one on the Phase III melanoma INT readout. Forgive me, but I have to ask for more granularity on timing. How close are you to achieving all the events required for the first analysis? What percentage of events for the first analysis have been observed? And what's your level of confidence that we'll get the data readout this year.

David Berman - *Moderna Inc - Chief Development Officer*

Tyler, good to hear from you. So we're not going to disclose any more details around the specific timing aside from that second half in terms of powering. I think in terms of confidence, the fact that we had this very strong randomized Phase II data that had consistent efficacy in all the subsets was very promising to me. And the fact, as I mentioned, that the translational data confirms the mechanism of action. I don't think that there's anything else that can be done ahead of a randomized Phase III. And so that's what we're conducting.

Tyler Van Buren - *Cowen and Company LLC - Analyst*

Got it. And if it succeeds in the Phase III, do you expect standard review? Or is a priority review possible? And can you remind us what your capacity to treat patients would be on approval?

Stephen Hoge - *Moderna Inc - President*

So priority review will always be subject to the data, but we certainly hope, certainly, if we're successful that it will be under consideration and then an accelerated review process is possible. As David said, we're highly confident we'll get that data in the second half of this year or at least that interim analysis will be completed. And if that is positive, again, we don't have the data yet. Then we would obviously make the case for an accelerated review, and we think it'll be supported by any profile that looked like the Phase II. Now as to commercial capabilities, we have been establishing the manufacturing in Massachusetts and a dedicated facility that will be able to support launch.

We believe that facility can support our commercial profile that ourselves and our partner, Merck, have articulated for several years to come. We hope we have to build more in the future if there's more demand, if all goes well. But we do believe we can satisfy the initial indication out of that facility and that we'd be ready to go next year if all went perfectly to plan.

Operator

Ellie Merle, Barclays.

Eliana Merle - *Barclays Services Corp - Analyst*

Just two for me, one on flu and then one on INT. Just in terms of flu, I guess curious if you've had any discussions with the FDA regarding strain selection for 2027, specifically, if there's a mismatch in the selected strains in the beginning of the year with the circulating streams later in the year, would you be able to update your strains the other flu vaccines wouldn't be able to. Basically, just curious if this came up at all in the discussions and how you're thinking about this as a potential possibility in 2027.

And then just a second question, INT interesting analysis on the immunogenicity that you presented at ASCO, curious if there's any learnings in terms of how you think about the algorithm for the selection of the neoantigen since there seems to be variability between patients in terms of the number of neoantigens that patients had immune responses for. So curious how you're thinking about that and potential ways that you could theoretically optimize the selection of the neoantigens.

Stephen Hoge - *Moderna Inc - President*

Thank you for both questions. So I'll take the flu one and obviously have David take INT. So first, in terms of discussions with US FDA. The answer is yes. Those have happened. In fact, they even happened at the advisory committee. And so there was active discussion both between the agency and the committee members as well as the company on how we would address a potential mismatch or a late strain selection.

Our demonstrated capability in the COVID context is less than 2 months, and so strain selections have happened as late as early July in the history of COVID, and we've been able to make a full vaccination season to work with millions of doses. And that was discussed at the VRBPAC and obviously had been part of the basis for pursuing accelerated approval in our discussions with the agency.

Now the process by which that would happen would ultimately fall to public health to articulate. And so FDA, CDC, WHO, others would need to accommodate a late strain selection if they wanted to. And those discussions, I would describe as in the early stage. The first step is to get the product approved. So there's a potential to address such a situation. And then the second step was to work closely with public health to define how we would do that and under what circumstances they would want us to do that.

David Berman - *Moderna Inc - Chief Development Officer*

Ellie, with regard to your second question, it's a very interesting question. So we see that about 29% of our neoantigens that go into our cassettes in general, are immunogenic. And the data that we showed is that for the patients that we showed, there were between 1 to 18 neoantigens that were reactive in each patient. So the good news is you only need 1 neoantigen reactive T cell in order for there to be activity. Of course, -- in theory, at least -- the more the better.

In terms of what we're doing, to improve. We do have an ongoing program to try and improve this algorithm. In fact, we're using artificial intelligence to try to develop the next algorithm. I think the key thing will be when we get an efficacy readout linking our algorithm to efficacy. I think that will be the next important step here.

Operator

Terence Flynn, Morgan Stanley..

Terence Flynn - *Morgan Stanley - Analyst*

Great. Maybe just on your flu vaccine, I was wondering if you could provide any update in terms of your thoughts on potential pricing either some of the inputs or how you're thinking about analogs there? And then on the norovirus interim, just any insight in terms of what that means for potential effect size.

Stephen Hoge - *Moderna Inc - President*

Great. Thank you for both questions. So first on flu pricing, look, it's a little premature. Those conversations are ongoing, but it's all subject to us getting the product approved, obviously. When we think about the positioning of that product, at least on our own with the data, we feel confident about that profile given the relative vaccine efficacy demonstrated in the Phase III trial.

It's been published in the New England Journal relative to standard dose that it really is in the enhanced category from our perspective and importantly, offers some features, for instance, the lack of egg adaptation that are even more specialized than some of the available therapies. And so we will be assessing from a health economic perspective, the potential value of those and in discussions with payers and other bodies, making sure that we characterize those potential benefits as we think about pricing in the future. But again, first step is let's get the product approved, which we're working on right now.

As it relates to norovirus, there will not be much more I can say than what we have right now because we are still -- the study is blinded and continuing. We have not previously disclosed the statistical analysis plan associated with it, so it would be inappropriate to do that now. Suffice it to say what we are doing is we know we will need additional cases from a further cohort to strengthen that statistical analysis and we're working hard on preparing to stand up that part of the study.

Operator

Cory Kasimov, Evercore ISI.

Cory Kasimov - *Evercore Inc - Analyst*

I wanted to also ask on Intismeran but on the RCC front. Can you speak to the immunogenicity data that you have that and it gives you confidence that Intismeran works as well in low TMB RCC as what you've seen so far in melanoma and non-small cell lung cancer.

David Berman - *Moderna Inc - Chief Development Officer*

So that trial is still ongoing. So we don't actually have that data yet. But we will be showing some data later this year on other tumors that are hard to treat. And I think the fact that we can demonstrate immunogenicity in, for example, pancreatic cancer, I think, leads us to believe that we can identify neoantigens and creates a neoantigen vaccine for RCC as well. I think we have confidence in that.

Stephen Hoge - *Moderna Inc - President*

And I think the one thing I'd add is at least in the context of our Phase II melanoma study, which is through 5 years, we had previously published that or presented that TMB did not correlate with a difference. In fact, low TMB melanoma -- adjuvant melanoma patients had a consistent hazard ratio as those with high. So it gives us some reason to believe that, that will translate, but to be fair, that is in the melanoma context. And as David said, we're still waiting for data in other histologies.

Cory Kasimov - *Evercore Inc - Analyst*

Yes. And I guess to be clear, I was wondering kind of where the confidence came from recognizing you don't -- we're waiting on that data later this year or next.

Stephen Hoge - *Moderna Inc - President*

And I think it comes from the lack of a role of TMB high versus low in driving the effect size that we saw in the Phase II and the totality of data we have around that.

Operator

Andrew Tsai, Jefferies.

Andrew Tsai - *Jefferies LLC - Analyst*

So just thinking about your Horizon 2 wave of assets coming. First, for the IDO compound, sounds like that could have pivotal data in 2027 since you mentioned it as a revenue contributor in 2028. So can you talk about what the approvable bar in first-line, second-line melanoma is? And then you also have a T cell engager program that you announced at the Science Day that I believe could have data at year-end. And so I'd be curious to know in a seemingly refractory population, would a positive data look like in myeloma? And is there a strategy for you to go upstream.

David Berman - *Moderna Inc - Chief Development Officer*

Andrew. So Horizon 2, so I'm glad you picked up on that. 4359, which is the IDO, PD-L1, is a very interesting program. There was proof of confidence from a randomized study from another company, which was very interesting. For us, we saw very intriguing data, which we showed last year, and we had a follow-up first-line data set earlier this year.

What we're doing now in the ongoing Phase II expansion is to confirm that signal - is the signal that we saw real, and is there a path forward based on that signal. And I think I don't want to get ahead of whether it's a pivotal or not. I think let's first confirm the signal. And identify what is the best opportunity in melanoma? Is it to go first line?

Or is it to go second line plus. I think as we all know, the bar in second -- in terms of your question about what is the bar for approval in second line for single-arm trials, it's a moving target as we see. I think suffice it to say that you have to show sufficiently high response rates that have sufficient durability. And I think no one really exactly knows what that definition of sufficiently high is. In terms of first line, we do have an ongoing combination with nivo/ipi.

We showed data earlier with pembro plus 4359, which was very intriguing. But we have to remember also that in single-arm trials, especially in the first-line setting, the combination of 2 active agents may sometimes be hard to disentangle what the activity is through. So we're looking for, can you safely combine them in first line? Do we see some signal of increased activity. And in second line in the PD-1 relapsed refractory, we're looking, do we see sufficiently increased signal of activity above what we would expect to see.

And in particular, in patients who progressed on prior PD-1s are we seeing durable responses. So more to come on that next year. With regard to 2808, which is the T cell engager program, this is something that's very interesting. So multiple myeloma, obviously, has a number of T cell engagers, and we recently heard this week from J&J, very exciting news about the first combination of 2 targets. That's the first time ever 2 T cell engagers have been combined.

And so for us, the reason we're excited is we have the first 3 T cell engagers in a single product ever being studied. And as you mentioned, we're setting this in relapsed/refractory myeloma in patients who progressed on multiple CAR Ts, on multiple T cell engagers, essentially patients who have no other options available. And so we're going to be looking -- first of all, can we produce 3 T cell engagers, number one? Is it safe and well tolerated number two, -- and is there evidence of complete responses and partial responses and how durable they are. That's, I think, what we're looking for.

But I'm quite intrigued and excited about both of these programs.

Operator

Courtney Breen, Bernstein.

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

Just a couple of others want to push a little bit further on norovirus and the update there. Obviously, the question that I think many of us are asking is, is this enrollment? Is this an efficacy? Or is this an event situation. And so perhaps if you can help us understand kind of the overall event rate relative to expectations and what might be driving that.

And then the second question is a little different. You obviously just announced a new Chief Commercial Officer into the company. And you've obviously got kind of a broadening business, particularly as we look at the pipeline and the number of readouts over the next couple of years. Can you just help us understand what are the top priorities for the Chief Commercial Officer over the next 6 months? And what might be the changes or the evolution required longer term with -- in the commercial structure to support this evolving business.

Stephen Hoge - *Moderna Inc - President*

I'll take the first question and then obviously turn it over to Stephane to handle the second. The first on the question of norovirus, limited in what I can say because the trial remains blinded, but suffice to say, we have -- we are going forward with another season this year. We have been able to enroll the trial, which I think was your question in the cohorts. But the epidemiology of the primary endpoint cases has been a little bit slower coming. As we had previously discussed, some of that in the first season for that trial, was the result of a unique outbreak of a different set of strains of norovirus that were not contributing to that primary endpoint.

And so cases came a little bit slower in that season. And for that reason, we were a little bit slower to achieve the interim analysis than we intended. We ultimately did though power the study for a final analysis, a full number of cases. And really, what we're doing now is we've kind of gone through that second season, been able to conduct the interim analysis is we're preparing for that third, which will be the third winter this year. This has happened with other vaccines in the past.

If you think about flu vaccines, they often have to do multiple season studies to accrue sufficient cases and did ultimately happen to us here or at least appears to have happened to us here. And so for that reason, we're getting ready to stand up that new case accrual. It's unique and that we have to enroll new patients to get new cases because it's a seasonal vaccine, a seasonal infection. And ultimately, we will go one more season we expect this winter for norovirus 1403.

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

Thank you, Stephen. Courtney, so in terms of context, as we talked about in the press release when we announced the position of Ester, basically, if you look at the business, as you know, we have 3 products on the market today. We have since the spring a fourth product approved d mCombriax, the flu/COVID combo, which we are preparing the launch for 2027, potentially a fifth product approved in H2, which, of course, we talked about before. So as you can see, just what is just in front of us is a very, very large growing ID pipeline of product.

And the other piece, as you know, is Europe, as you know, we have not been able to participate in the EU market because of an exclusive partnership that the EU has set up during the pandemic, but this partnership expires, as we've said before in 2026.

So we really see Europe as a very important growth driver for us. And as you know in Europe, the markets are all very, very different. So there's a lot of complexity there. And then, of course, there is INT. As we said, we expect Phase III data potentially in the second half of the year, given the trend.

And so as you can imagine, Moderna and our Merck colleagues have been very active. Stephen talked about manufacturing a minute ago, but we have been very active on the commercial side of the house in terms of medical affairs, marketing, commercial. And so that's another piece where Ester's also going to be helping and leading working hand in hand with Merck. And of course, there's also a rare disease with PA. As you know, we've said PA because it's a time-driven Phase III, we should have data this year.

Of course, it's our partner Recordati, but we're going to be, of course, working with our partner to ensure a great launch. So if you look at the next few years, Stephen has a good slide earlier in the presentation, looking at the geographic expansion including also in Asia and Latin America, the product expansion. So there's a lot to do. And so as we are gearing for the growth stage of the company coming ahead of us, we thought that this role was important. And also the new role for Stephen, who is really overseeing ID, INT and rare from kind of general management to make sure that all the functions are integrated together.

So it's just us getting ready for the next stage of growth of the company that is exciting.

Operator

Michael Yee, UBS.

Michael Yee - *UBS AG - Analyst*

We have two questions. First is on INT for David or Stephen, at the interim analysis, while you're not going to disclose the powering, if you go back to your Phase IIb, it was statistically significant, but you were using a 1 sided alpha of 0.1. And so that's a much different hurdle rate than, say, traditional interims that you might be using here. So to what extent that people have too high expectations for the interim versus the final where you could have a nonproportional hazard ratio where the effect size gets better over time due to the way the drug works. That's question number one, is the thought around the effect size is getting better over time in a nonproportional hazard ratio.

The second question is on the COVID flu combo in Europe. Can you just remind us at what point you engage in conversations to do contracting for that? Because I guess you could have actually have revenues for that in '27 and when we get visibility on that?

David Berman - *Moderna Inc - Chief Development Officer*

Michael, I'll take the first question. So we are not going to disclose anything on the statistical analysis plan. But I do think there is maybe 2 key points to highlight. The first is if you remember back to the Phase II study, of course, updated at ASCO. There was, as you said, somewhat of a nonproportional hazard with about 12 months for really strong separation to occur.

The good news in the Phase III study, which was designed with Merck, who has a lot of expertise in melanoma is that it requires also a minimum of 18 months follow up. And so every patient has been followed way beyond where they were after the separation occurred. So I think that with regard to that, that gives us increased confidence. Stephen, the second question?

Stephen Hoge - *Moderna Inc - President*

Yes. On the question of combo in Europe and negotiations, so with approval, we can start the pricing negotiations with many governments where that is a separate process. And so in most cases, we have then submitted those HTA documents as health technology assessments or the supporting pricing negotiations are underway. In some cases, you need the recommending body, (sort of analogous to CDC), recommending body recommendations before you engage in that process. And in all those cases, we've been supporting those.

Some of that has been happening publicly. And so you'll see recommending bodies in countries like Germany, where others have begun to contemplate the combo vaccine and then as I said, in other countries where we've begun those pricing negotiations. There are first instances of pricing being issued in a couple of countries, and we'll continue that process through this year. Once that's there, we will have achieved market access, and then we'll be in the process of engaging in tenders or in countries that are not tender countries in Europe, in commercialization and straightforward commercialization.

About half of those markets will be more tender related. Some of those tenders will deal with 2027. Some of those tenders will deal with 2028 because the timing of their flu or COVID tenders are maybe a year forward. And we'll provide more clarity on that as we get into that year. So we would expect some contribution from traditional commercialization markets as well as tender markets beginning in 2027.

But the full effect really probably not felt until 2028 and maybe a little bit beyond, depending upon what individual countries require from real-world effectiveness data or other things post approval to support market access. So we're excited to be approved. We have a lot of work to do in Europe to drive that growth. We think that there's real enthusiasm for the product. Obviously, we have it ourselves. And we're working hard to start impacting as early as '27, but really build the business over the couple of years thereafter.

Operator

Geoff Meacham, Citigroup.

Geoffrey Meacham - *Citi - Analyst*

I just had a couple of quick ones. I guess for Jamey, the 10% revenue growth guidance for the balance of the year. Maybe just give us a reminder of the puts and takes of that when it comes to different geographies? Are there still more contracts or more sources of potential new pockets of demand. And then on the rare disease portfolio, you guys have completed enrollment in 39 27. Just wanted to get a sense for what determines the timing, maybe the regulatory usability of the readout, I wasn't sure what you guys are looking for from an effect size or from clinical meaningful standpoint.

James Mock - *Moderna Inc - Chief Financial Officer*

Yes. Thanks, Jeff, for the question. I'll take the first one on revenue. So we're sitting pretty good after the first half year in terms of $0.5 billion in revenue, roughly 70% international, 30% in the US. And your question is getting at, where is the upside?

Where is the variables to the second half. So I just want to start by saying, if you look at our first half, we are up almost $300 million versus the prior year. So if we are flat in the second half, that would actually be above 10% growth for the year. So now what are the variables to the second half. If you look at the -- what we said is we're basically 50-50 for the entire year, US

versus international. So obviously, having a higher percentage in the first half international, that means we have a higher percentage in the US. And that's really where the biggest variable is. So across the globe, we've basically contracted. We have to execute.

There are some countries that have minor vaccination rate. Some shipments could happen into the year or some could go into the first quarter of the following year, but I would call that relatively small. I think the biggest variable comes down to the US. And we've provided

for, as I mentioned in my prepared remarks that we have provided for a vaccination rate decline, particularly in the US. And so the biggest upside swing is if it is not as big a decline as we projected, then we should have upside in the US.

If it's worse than we projected, then obviously, there would be a downside to that. And so if you just kind of think about the second half in terms of broad pictures, and I kind of said this on the last call, is in the second half international, last year, we had no UK volume and not some of the strategic partnerships volume. This year, we will supply some of the strategic partnerships that we have, and it's quite material. And that's basically the upside that is offsetting the provision that we put in to the US

in terms of vaccination rate declines. So for the most part, we're really confident we've got a substantial growth through the first half here. If we are flat to last year with international growing and offsetting the US decline, then we should be above our 10% guidance, and the biggest variable at this point is just what is the size of the US market?

David Berman - *Moderna Inc - Chief Development Officer*

With regards to the question on PA, the time -- it's around 20 patients were enrolled and the primary endpoint, which is metabolic decompensation events on treatment relative to pretreatment so each patient serves as their own control is based on a 12-month follow-up. And so that should happen sometime in fourth quarter. And just as a reminder, in our prior releases, we showed about a 60% to 80% efficacy with our therapy. And so that's why we have confidence or hope for this trial.

Operator

Myles Minter, William Blair.

Myles Minter - *William Blair Capital Partners - Analyst*

My question is just one on clarification. I think Dr. Carlino at ASCO mentioned in Interpath-001 that approximately 2/3 of patients would have micrometastatic disease. It's a little bit confusing to me as to whether that was just restricted in the Stage III patients. So that was the overall trial.

So just wondering whether you can confirm or adjust his comments that are set on record. And then secondly, just the potential impact of going from a third micrometastatic in the Phase I/II study to 2/3 into Interpath-001 and any sort of impact that we could see there.

David Berman - *Moderna Inc - Chief Development Officer*

So I don't recall exactly what he was referring to in that statement. But the trial -- we haven't released the baseline demographics of the trial. So essentially to say that it's Stage IIb to fully resected Stage IV. And in terms of why we believe we can go to that broad eligibility based on the Phase II data, it's because when you look at the subsets of -- from an efficacy standpoint, they were all consistent. And secondly, we know that the earlier you go, i.e., Stage IIIa and then Stage IIb and IIc.

The immune system should be healthier, the tumor burden should be even lower. And so the ability to induce a T cell response and to have those T cells kill, whether it's micrometastatic or still even before it's micrometastatic should still be there. So I think that's what I would say. I don't remember exactly the point about 2/3 micro metastatic.

Operator

Jessica Fye, JPMorgan.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Just wanted to confirm two things on INT. First, if the interim in the Phase III adjuvant melanoma trial passes without stopping for efficacy. How will the Street learn about that? I guess, is the study simply continuing, a material event that we would hear about right away? Or would we just hear about that maybe later in normal course updates.

And then the second one on INT. In the translational poster at ASCO -- had a relatively small number of patients relative to the number who were in the Phase II? I'm curious if you know what the data looks like in the broader study population.

David Berman - *Moderna Inc - Chief Development Officer*

So we will be issuing a press release on that data, Jess for the interim. And with regard to the second question, the reason that the data set on the translational was only 7 patients is because that in-depth T-cell antigenicity required leukophoresis, which is a little bit more burdensome to the patients than just collecting a tube of blood. And so the patients have to consent to that. And we do hope to expand that because we do think that, that degree of biomarker analysis is important for understanding the mechanism of the drug. And actually, we're also looking at ways and we're exploring ways to try and disentangle T cell immunogenicity without having to do leukophoresis. So that's still exploratory, but more to come on that. That's the reason why there were only 7 patients.

Operator

This concludes our Q&A session. I'd like to turn the call back to Stephane for any remarks.

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

Thank you very much, everybody, for joining. We look forward to speaking to many of you in the coming days and weeks, and have a great day and weekend. Bye.

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.