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MRNA.OQ - Q1 2026 Moderna Inc Earnings Call

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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to Moderna's first 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, Head of IR. 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 today to discuss Moderna's first quarter 2026 financial results and business updates. You can access the press release issued this morning as well as the slides that we'll be reviewing by going to the Investor section of our website.

On today's call are Stéphane Bancel, our Chief Executive Officer; Stephen Hoge, our President; and Jamey Mock, our Chief Financial Officer.

Please note that this conference call will include forward-looking statements made pursuant to the Safe Harbor provisions 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 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 Stéphane.

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

Thank you, Lavina. Good morning or good afternoon, everyone. Thank you for joining us today.

I will start with a review of our first quarter. Jamey will then cover our financial results and outlook, followed by Stephen on commercial and clinical progress. I will close by discussing our value drivers before we take your questions.

The Moderna team delivered a great quarter all around. In the first quarter, we grew year-over-year revenues significantly to $0.4 billion, driven primarily by execution of our long-term strategic partnership with the UK government. With a strong Q1, we are reiterating up to 10% growth in 2026. We reported a net loss of $0.5 billion excluding the previously announced Arbutus litigation settlement or $1.3 billion on the GAAP basis.

We ended the quarter with $7.5 billion in cash and investments, maintaining a strong balance sheet as a result of continued financial discipline. Our cost reduction efforts continued in the first quarter, building on actions taken in 2025 and resulting in a 26% year-over-year reduction in adjusted cash cost in the first quarter, excluding litigation settlement. This performance keeps us on track with our full year objective of approximately $4.2 billion in adjusted cash cost.

We also advanced our commercial portfolio and our pipeline. In our respiratory portfolio, we achieved an important milestone with the approval of mCOMBRIAX in the European Union. mCOMBRIAX was known before as mRNA-1083 or flu plus COVID combo vaccine. This is the first flu plus COVID combo vaccine approved in the world, and this marks Moderna fourth approved product. I am very proud of the team for bringing this innovation to patients. This is exactly what Moderna stands for.

We also secured approval for Spikevax in the European Union. These two new approved products in Europe will be important growth drivers in the EU in 2027, and when we anticipate the COVID market reopening for Moderna. In the US, our seasonal flu vaccine, mRNA-1010, was assigned a PDUFA date of August 5.

In oncology for intismeran, we initiated a new Phase 3 clinical trial in non-small cell lung cancer for patients with Stage 1 disease. This is our first Phase 3 clinical trial evaluating intismeran in a monotherapy arm in patients with early-stage disease. I am very excited about this new clinical development because Stage 1 lung cancer is mainly treated with surgery alone today.

Additionally, we look ahead to our upcoming ASCO oral presentation, where we'll report a five-year update of our intismeran in adjuvant melanoma. We were also pleased to recently present at AACR the new clinical data for mRNA-4359, which is currently in Phase 2 for patients in Stage 4 disease, metastatic in melanoma and lung cancer.

Lastly, with support from CEPI, our pandemic flu program, mRNA-1018, has now initiated its Phase 3 study. I'm very pleased with the company's strong performance in Q1 and very thankful for our team that executed across the board.

With that, I'll turn over to Jamey.

James Mock - *Moderna Inc - Chief Financial Officer*

Thanks, Stéphane. And hello, everyone. Today, I'll cover our first quarter financial results and then review our 2026 financial framework.

Let me start with our commercial performance on slide 7. For the first quarter, total revenue was $400 million, coming in above our guidance and represents a $300 million increase versus the prior year. Our geographic mix was approximately 80% from international markets and

20% from the United States. This strong international revenue performance was primarily driven from deliveries under our long-term strategic partnerships.

For the second quarter, we are expecting revenue of between $50 million and $100 million, evenly split between US and international markets, which would bring our first half revenue to approximately $440 million to $490 million. Our strong revenue performance year to date puts us on a solid path to achieve our full year revenue growth target of up to 10%, which we are reiterating today.

Now I'll round out our full first quarter financial performance on slide 8. As I just mentioned, revenue was $400 million in the quarter. Cost of sales for the quarter was $955 million. This includes $878 million related to our previously disclosed litigation settlement. Excluding this item, cost of sales was $77 million, a 14% year-over-year decline on a non-GAAP basis, driven by reduced unutilized capacity costs, losses on purchase commitments and inventory write-downs, partially offset by higher sales volume.

Regarding the litigation settlement in March, we announced that we entered into a settlement agreement with Arbutus and Genevant, resolving all litigation with them worldwide. Under the deal terms, we will make a lump sum payment of $950 million in the third quarter of 2026, of which $878 million was recognized in cost of sales during the first quarter of 2026, and the remaining $72 million is being amortized over the next three years.

Under the agreement, Moderna will appeal to the Federal Circuit to argue its government contractor immunity defense, which limits its liability under Federal Statute 1498. If Moderna ultimately prevails on that issue, no further payments will be due. If, however, the Federal Circuit affirms liability under Section 1498, Moderna has agreed to make an additional payment of up to $1.3 billion. We have concluded that a loss related to this pending Section 1498 proceeding is not probable, and accordingly, no charge has been recorded.

R&D expenses for the quarter were $649 million, a 24% decrease compared to last year, driven by lower clinical development and manufacturing costs as we wind down large Phase 3 respiratory programs and our CMV Phase 3 study, partially offset by higher post-marketing commitments from our COVID products. SG&A expenses for the quarter were $173 million, an 18% decrease compared to last year, driven by lower spend across all functions, reflecting continued cost discipline while supporting the business. 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 $1.3 billion or $3.40 per share, compared to a net loss of $1 billion or $2.52 per share last year, primarily driven by the litigation settlement. Excluding this item, the net loss would have been $0.5 billion or $1.18 per share, down over 50% versus the prior year.

We ended the first quarter with cash and investments of $7.5 billion compared to $8.1 billion at the end of 2025. The decrease was primarily driven by operating losses as we continue to invest in R&D and advance our pipeline. The litigation settlement did not impact cash in the first quarter, as the $950 million payment is due in the third quarter of 2026.

Now let's turn to our financial framework for 2026. As mentioned earlier, we expect total revenue to grow up to 10% in 2026, with a geographic mix of roughly 50% from the US market and 50% from international markets. Our 2026 revenue guidance factors in potential future declines in COVID vaccination rates, offset by increased penetration of mNEXSPIKE and revenue from our long-term strategic partnerships. As a reminder, this guidance assumes no revenue from our flu vaccine or mCOMBRIAX.

Our cost of sales projection has increased from $0.9 billion to $1.8 billion and now includes the $0.9 billion litigation settlement charge. Without the litigation charge, our cost of sales projection would have been unchanged versus our previous guidance and reflects our expectation of gross margin improvement from manufacturing efficiency gains and volume leverage.

R&D expenses are still anticipated to be approximately $3 billion as we continue to invest in our pipeline while maintaining financial discipline. We now expect the timing of our R&D spend to be slightly weighted more to the second half of the year. 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 commercial business. In aggregate, excluding the $0.9 billion litigation charge, we are expecting total GAAP operating expenses of $4.9 billion and cash costs of $4.2 billion, which excludes stock-based compensation, depreciation, and amortization.

Additionally, we do not see any material impacts from the ongoing conflict in the Middle East to our 2026 financial outlook. But we'll continue to monitor geopolitical developments.

We expect taxes to be negligible in 2026. Capital expenditures are still projected to be between $0.2 billion and $0.3 billion. We expect to end 2026 with between $4.5 billion to $5 billion of cash and investments.

Our cash guidance does not assume any additional drawdown from our remaining $0.9 billion undrawn credit facility. Overall, we are encouraged by the strong start to the year and remain focused on executing in Q2 and beyond.

With that, I will now turn the call over to Stephen, who will walk through the commercial outlook in more detail.

Stephen Hoge - *Moderna Inc - President*

Thank you, Jamey. And good morning or good afternoon, everyone. Today, I'll review our commercial outlook as well as progress across our pipeline.

Slide 11 outlines our multi-year revenue growth strategy, anchored in both geographic expansion and continued advancement of our product pipeline. In 2026, as Jamey mentioned, we expect up to 10% revenue growth, 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 three-year horizon, we're building a diversified portfolio, adding a flu vaccine, a combination vaccine, and a norovirus vaccine, as well as late-stage assets in oncology and rare diseases, and all while expanding our global footprint into new markets.

We made good progress against this strategy in the quarter. We delivered our first shipment under our strategic partnership in the United Kingdom. We secured key regulatory approvals in the European Union, including mNEXSPIKE for individuals 12 and older and mCOMBRIAX for adults 50 and above, positioning us well in the large $1.8 billion annual European respiratory vaccines market.

We expect both products to contribute to revenue growth starting in 2027. And in the US, our flu program continues to advance with the PDUFA date set for August 5, 2026. Stepping back, our execution in the quarter gives us confidence in our ability to deliver in the near term and to grow over the long term.

Slide 12 highlights our approved products within the infectious disease portfolio. With the recent EU approval of mCOMBRIAX, we now have four approved products, a remarkable milestone for our commercial portfolio.

Starting with our COVID vaccines, we plan to submit annual strain updates across all approved geographies shortly. More than 30 countries for Spikevax, and in the US, Canada, and Australia, and now the European Union for mNEXSPIKE. mNEXSPIKE also remains under review in Taiwan, Japan, and Switzerland, with additional filings planned for the second half of 2026 to further expand global access to this important vaccine.

Turning to RSV, mRESVIA is approved in the US, European Union, and Canada. Most recently, the European Commission also extended that approval to expanded indications to include adults aged 18 and older, broadening the eligible population.

For our flu plus COVID combination vaccine, mCOMBRIAX, we recently received approval in the European Union for adults 50 and older. The product is also under review in Canada and Australia. We are waiting further guidance from the FDA on the next steps for resuming filing in the US.

Finally, at ESCMID, we presented new data supporting heterologous vaccination with mRESVIA, as well as results from a Japanese cohort from our Phase 3 mCOMBRIAX studies. Links to both presentations are included on this slide.

Our late-stage infectious disease pipeline also continues to progress. Starting with flu, mRNA-1010 is under review in the US, Europe, Canada, and Australia, and the US FDA PDUFA date is set for August 5. We recently presented revaccination data for mRNA-1010 at ESCMID, with a link to the presentation included on this slide.

And for our norovirus vaccine, our ongoing Phase 3 study is now fully enrolled in its second Northern Hemisphere season. Based on case accrual to date, we continue to expect data from this study in 2026.

Turning to oncology, starting with intismeran, our individualized cancer therapy developed in partnership with Merck. This trial program continues to expand, with nine ongoing Phase 2 and Phase 3 studies. As Stéphane previously mentioned, we have initiated another Phase 3 study in non-small cell lung cancer, our third Phase 3 in lung cancer.

This one is in high-risk Stage 1 disease, expanding us to the earliest stage of the disease. The trial includes an evaluation of intismeran as a monotherapy. This is our second monotherapy study following our non-muscle invasive bladder cancer study announced previously and highlighting intismeran's safety and tolerability profile as we move into earlier stage disease.

Across the portfolio, we now have multiple late-stage studies fully enrolled, including Phase 3 adjuvant melanoma, as well as Phase 2 studies in renal cell carcinoma and muscle-invasive bladder cancer, all of which are accruing events towards their interim readouts.

We continue to make progress towards completing enrollment in our other Phase 3 and Phase 2 trials, including in non-small cell lung cancer, bladder cancer, and metastatic melanoma. This broad late-stage portfolio is supported by the strong clinical data, including robust five-year results from our Phase 2 adjuvant melanoma study, which will be presented at ASCO. Beyond late-stage programs, our Phase 1 studies in pancreatic and gastric cancers are also fully enrolled, and we look forward to providing updates on those trials later this year.

Now, outside of intismeran, we continue to advance additional oncology programs. For mRNA-4359, our cancer antigen therapy, Phase 2 cohorts are enrolling across first-line metastatic melanoma and first-line metastatic non-small cell lung cancer. We recently presented new data in first-line metastatic melanoma setting at AACR, with a link to the presentation included on this slide.

And finally, our early-stage pipeline continues to progress, including our T-cell engager mRNA-2808 in a Phase 1/2 study, a cancer antigen therapy mRNA-4106, and cell therapy enhancer mRNA-4203 in Phase 1 studies in patients actively dosing.

Now in rare diseases, our propionic acidemia, or PA program, is fully enrolled in its potentially registrational study. We continue to expect pivotal data from this study later in 2026.

For our methylmalonic acidemia, or MMA program, we have decided to defer the start of a registrational trial for that program until after we receive the pivotal readout from the PA, or propionic acidemia program later this year.

With that review, I will hand the rest of the call over to Stéphane.

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

Thank you, Stephen and Jamey. Looking ahead to 2026, we see multiple value drivers across our company in commercial, in new product approvals, and in late-stage pipeline.

On the commercial side, we continue to expect up to 10% revenue growth and remain focused on delivering our adjusted cash cost target of approximately $4.2 billion. We continue to invest in AI with a number of cross-enterprise projects to reinvent work with AI. We will of

course, continue to drive increased personal productivity across the company. We also expect potential approvals across the respiratory portfolio in additional geographies. We could, later this year, see our fifth product approved with mRNA-1010 for flu.

From a pipeline perspective, oncology remains a key focus with upcoming data for intismeran and mRNA-4359. We're also waiting for the Phase 3 data for norovirus subject to case approvals and of our PA programs, which should read out this year. The team remains focused on disciplined execution across these priorities.

Over the coming months, we also look forward to engaging with the investment and medical communities at several upcoming events. This includes our investor event on June 1 at ASCO, but also we would like to invite you in person to Cambridge via webcast for our Science Day on June 25, where we'll provide a deeper look into our early-stage pipeline, but also how we're using AI and robotics to accelerate our ability to discover new technology to expand the use of mRNA to new drug modalities. On November 12, we'll also host our annual Analyst Day, where we plan to focus on commercial priorities, product launches, and expanding late-stage pipeline.

In closing, I want to thank our teams around the world for the progress we've delivered this quarter. We have been executing consistently over the past year and a half. I'm very excited of what is to come in 2026 and beyond. We are advancing our science, expanding our portfolio, and continuing to translate mRNA into innovative medicines for patients. Each milestone achieved adds important momentum and reconfirms our commitment to deliver life-changing impact to people for mRNA medicine.

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*

So you newly disclosed initiation of a Phase 3 study for Intismeran as monotherapy and in combination with KEYTRUDA subcu for the treatment of high-risk Stage 1 small cell lung. Can you just -- and you spoke to it a little bit, but could you discuss your strategy to pursue this line and where it fits into the treatment landscape and why pursue a monotherapy here in addition to the combination?

Stephen Hoge - *Moderna Inc - President*

Yes. Thank you for the question, Salveen. We and our partner, Merck, have been really excited by the clinical data that we've seen with Intismeran to date, including the Phase 2. And it's important to highlight that the two pieces of that, one is obviously the efficacy signal we see, but the second is the remarkable safety profile associated with that efficacy, really no significant increase in serious or Grade 3 events when you get combination IO-IO like benefit.

So the real question for us has been could we get that benefit risk profile in a monotherapy context? Could Intismeran provide IO-like protection against a relapse or recurrence of disease with a profile that really looks like a vaccine? And the best opportunity for us to do that, we and Merck have decided is it's across a couple of studies.

Now the first I previously discussed was in bladder cancer, but we ultimately decided that in lung cancer, given the incredibly high burden of disease, the right approach there was to go into a Phase 3 potentially pivotal study.

In that context, as Stephane mentioned, as you referenced, standard of care, more often than not a surgery and then watchful waiting. And so essentially, there is no other intervention. And we're looking at, therefore, INT as monotherapy as opposed to just surgery and watchful waiting for high-risk Stage 1 disease.

Now we're also going to look at whether or not there's an incremental benefit of combining INT with KEYTRUDA in that setting because obviously, the best way to address cancer is to have it never occur after Stage 1. Unfortunately, what happened in the treatment landscape is many of those Stage 1 patients will recur, sometimes even recur as Stage 4 or metastatic disease, and that is when we're fighting very late to try and control a quite progressed cancer.

And so our goal, simply put, is to intervene early, prevent the relapse or recurrence from ever happening and in so doing, try and achieve cures in the earliest stages of disease. Benefit risk there needs to have a very good safety profile, and we really do think that the monotherapy safety profile of INT will be really strongly supportive if we can see in that Phase 3 study a strong efficacy signal.

So we and Merck have been talking about this one for a while. Our strategy has been to focus on the adjuvant settings, but we have -- and we have started, as you know, some metastatic studies, but we have always wanted to move earlier, signaled that from the beginning because of that benefit/risk profile of INT and we are really excited to see the potential now in Stage 1 disease in a Phase 3 lung cancer trial.

Operator

Jessica Fye, JPMorgan.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

With a significant amount of international sales this quarter, I remember the -- I think the UK order from last year got pushed into early '26. I'm just trying to think about those contracts and the right way to think about what more could come from the UK for the remainder of '26? Like is it possible this is a double order year? And maybe you could just elaborate on how that works?

Stephen Hoge - *Moderna Inc - President*

Yes, sure, I'll take that. And so the delivery that happened in the first quarter is for their spring campaign. And so for -- in the United Kingdom, there's a recommendation for both spring and fall booster for the targeted population does over the age of 75 or with significant risk factors. And so a second campaign is planned for the fall, and so the third and fourth quarter of this year, and that would be an additional delivery later this year.

Operator

Terence Flynn, Morgan Stanley.

Terence Flynn - *Morgan Stanley - Analyst*

Great. Just wondering if you can be any more specific about the timing of the interim Phase 3 of the INT and adjuvant melanoma. I know you said 2026, but can you refine that at all at this point? And then maybe talk to the range of potential outcomes there? Are there only two outcomes, either the trial hits at the interim and continues as planned? Or is futility also a potential outcome on this interim?

Stephen Hoge - *Moderna Inc - President*

Yes. Thank you for both questions. So I will disappoint in the sense that we won't refine that guidance. We have said we are confident based on the event accrual that we will see interim analysis conducted in 2026. I shouldn't say more, except that, that confidence should indicate where we think we are. On the question of the outcomes, there is not a built-in futility assessment.

The interim analysis is either to declare early success or to continue to accrue events in the trial towards a subsequent interim analysis or final analysis both of which could happen in the years ahead. The study is very well powered and has been balanced in terms of its accrual. And so we have continued to accrue events in a way that we would expect, and therefore, we're optimistic about that interim analysis. But obviously, if we have not yet hit the critical hazard ratio to declare early success, we will have the benefit of continuing to look at more events afterwards, but futility is not a part of the current plan.

Operator

Luca Issi, RBC.

Luca Issi - *RBC Capital Markets Inc - Analyst*

Great. Maybe, Jamie, on IP, can you just walk us through why the legal team deemed the additional $1.3 billion charge on 1498 is not probable. I guess the question is what gives you confidence that you will ultimately prevail there? And then maybe just kind of bigger picture, remind us that time line of when the final ruling could come?

And then maybe quickly, Stephen, what's the latest thinking on flu in the US ahead of PDUFA? We obviously now have a new acting director (inaudible). So I wonder if you have had any interactions with her, and whether you think that having her need is incrementally positive or incrementally negative for you? So any color there, much appreciated.

James Mock - *Moderna Inc - Chief Financial Officer*

Yes. Thanks for the question, Luca, I think I may disappoint as well because we're not really going to comment too much on the merits of the trial. So all I can say is our legal team and ourselves, we are confident, and therefore, we believe it improbable that we would lose and therefore, have not recorded anything. From a time line perspective, it's always difficult to exactly read, but we think that it could be perhaps late 2027 maybe into 2028 is where we think that this might be resolved. But again, that's a moving target.

Stephen Hoge - *Moderna Inc - President*

And for the question on the FDA and the -- particularly the flu 1010 program, we continue to progress well in that review in the normal back and forth with the review team and the folks in the office of vaccines towards our PDUFA date, obviously, at this point through a mid-cycle. And we would describe that as a pretty normal course, the kinds of exchanges we're having. And so we're encouraged by that and look forward to that August 5 PDUFA date. Obviously, we'll work hard to answer any questions, any remaining questions that the FDA has as they complete that review.

As to the senior leadership, whether it's (inaudible) or otherwise, we don't usually interact with them in these reviews at all. Really, this is the review staff, the folks in the office of vaccines, and that is the only place that we've been going back and forth. And we don't expect any impact, certainly didn't before, today or after as a result of the new Acting Director.

We do look forward to working with the leadership of (inaudible) broadly across our portfolio. So the 1010 flu vaccine review continues somewhat independently, but we have a large portfolio of other products from in Intismeran, INT to norovirus to our first rare disease program, the propionic acidemia program, all of which we hope have pivotal readouts this year, and we look forward to bringing those

forward. So it's an exciting time for us, hopefully, for the field, and we are very grateful for the partnership across FDA and CBER as we try to bring these medicines forward to patients.

Operator

Tyler Van Buren, TD Securities.

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

Congrats on the quarter. For the Phase 3 Intismeran adjuvant melanoma top line data, can you remind us what it is powered for? And perhaps more importantly, can you give us your latest thoughts on what constitutes success from a clinical standpoint? And what you need to show in RFS on an absolute basis or as we think about relative benefit there?

Stephen Hoge - *Moderna Inc - President*

Thank you, Tom, for the question. So we haven't disclosed the powering assumptions for the IA. Suffice it to say, we -- the Phase 2 data had a really strong hazard ratio, very narrowly missed and a substantially smaller powering 150, 160 participants as opposed to 1,100. And so we're -- we think we are well powered -- very well powered if we see a similar hazard ratio. That would obviously be a huge success.

But to your second part of your question on sort of the range of things that we would be pleased with, obviously, anything looks like the Phase 2 would be spectacular. But candidly, we think the opportunity for benefit could be anywhere between that 1.5% that we saw in a number like 0.8, where there's a significant benefit still in terms of survival and treatment of melanoma -- adjuvant melanoma, Stage 2 melanoma.

Now across that range is a wide range of outcomes that we want to understand the raw data in what's happening. If you see really strong RFS and really strong eventually overall survival, as we've seen so far in the Phase 2 study, that's encouraging. If you saw maybe the overall survival or just a (inaudible) data was better even if the RFS was not, that would probably equally be encouraging. And so there's a range of outcomes for how we would declare success that will depend upon the different clinical benefits that we see in the study.

But for now, we feel like we are well powered going into that interim analysis. If not, we look forward to the subsequent analysis. And we think there are a range of outcomes here ranging from the Phase 2 results to a whole bunch of events that are much more modest, that could still be really meaningful patients and move forward successfully commercially as a treatment for Stage 3 mono.

Operator

Ellie Merle, Barclays.

Eliana Merle - *Barclays Services Corp - Analyst*

Curious what your expectations are for timing for data from RCC and muscle invasive bladder cancer. And can you elaborate on what good data would look like in these indications? And then what the next steps would be in those indications if the data are positive?

Stephen Hoge - *Moderna Inc - President*

Yes. Thank you for the question. As we've previously said, both of those randomized Phase 2 studies are fully enrolled, about 300 participants in each. And so we're really excited to to fill in the picture on the strength of performance for INT across a range of different tumors. I would

point particularly to the RCC as one that we're we're interested to see whether or not we can provide a really meaningful clinical benefit because we still think there is an opportunity, headroom for improvement there that's quite significant.

Now those are event-driven trials, and we did want to protect the registrational possibility for those trials. So we're blinded, and we're accruing events towards that first interim analysis in both. For obvious reasons, we -- if possible, we would want those studies to be registrational. And so we want to make sure we accrue a good number of events and that we treat those analyses the right way. And because that it's hard to guide right now.

We don't exactly know when potentially this year or even early next year that those results could come in because they are event-driven analysis. But when we have accrued sufficient cases to conduct that blind analysis, we will definitely be doing so. And all of us are eager to see the results because it will help not only guide whether or not those products or those indications are reasonable to move forward more quickly, again, potentially to a registrational study or towards a Phase 3 pivotal study, which we would look to start quickly.

But also, they feel in that picture of how broadly INT is going to play. And in some ways, if you think of RCC as an example of a place where it's relatively far from melanoma in terms of mutational burden, and therefore, an opportunity for us to demonstrate a potential benefit that would then widen the aperture of where we think INT might have a role.

So we're keen to see that data, but we are blinded at this point. We're following those events, and we are eager to provide updates once we have more. But for now, we can't guide on when that timing would be.

Operator

Michael Yee, UBS.

Michael Yee - *UBS AG - Analyst*

We have two questions on INT. The first was on the melanoma study. Would we expect that, that's a similarly designed protocol as it relates to the interim? I recall that the Phase 2 strongly hit at the interim. And so just trying to understand if a similar type of standard interim was built in here such that if it doesn't stop at the interim, it would imply some sort of different hazard ratio for the first term versus the second room?

Similarly, on the renal study, we understand that this is a much slower progressing tumor if you look at the KEYTRUDA adjuvant studies, just trying to understand how it would be possible that a potential interim would come this year, or that's a much differently designed study in terms of an interim?

Stephen Hoge - *Moderna Inc - President*

Yes. Thank you, Michael, for both questions. So first, we obviously haven't given any statistical guidance on the Phase 3 interim analysis. But suffice it to say, I just did a moment ago. We wouldn't be conducting the interim unless we thought there was a chance of success. And in that sense, we are not defining that as the hazard ratio that existed in the Phase 2. There were some differences in the population, but certainly, that would be a situation we would want to have a relatively early look at. And so it's somewhere between there and obviously, not significant that we're looking for.

We are -- we have -- we are really excited, but we also just need to wait and let the data mature and see those results. And so we're optimistic about that first interim. But it's fair to say that if it isn't successful, there's still opportunity in the second and the final. And we definitely have reserved alpha for both of those for what we think would still be commercially important products. So that's Point 1.

Now on the renal, the renal is -- RCC is, as you said, the events can happen more slowly. There is a benefit, obviously, from KEYTRUDA, but there's a substantial headroom still. Even if you look to the combination products, KEYTRUDA plus Bezu, Merck has just had a great success there, with a hazard ratio of 0.72, there's still headroom even above that for improvement in terms of disease free survival. And so we're keen to look at that result. There are about 300 participants enrolled in that study. And I'll remind you as a reference, that's about twice as large as the Phase 2b adjuvant melanoma study that we've all been speaking so much about.

We're not intending to power that as a registrational study, but it has registrational potential. And what that means is we could have a lower statistical threshold for declaring that there's a strong result there, a strong signal, I think, again, like what we saw in the Phase 2b with melanoma. The key there though, would be we would not want to unblind that study if at a lower threshold, call it 0.1 -- alpha 0.1, we wouldn't want to unblind the study if it was trending towards statistical significance and registration potential. And so that's the key unknown in that RCC study in terms of timing is we will hit a trigger for conducting human analysis based on events. The DSMB will look at that result and then advise us whether it's appropriate to declare early success or whether to remain blinded or alternative outcomes that are more like futility, but that would cause us to want to look at that data and quickly determine whether or not we want to run a Phase 2.

And so it's a high degree of uncertainty of what that looks like, but it's all about trying to make sure that if we have a drug here, a strong signal in RCC with registrational potential, we did not disrupt that. Or if it's strong, it needs a Phase 3 more powered analysis that we get that going quickly. And I think that's the decision that lies ahead of us in partnership with the DSMB.

Operator

Courtney Breen, Bernstein.

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

Just a couple more on INT. What I wanted to understand as we're getting closer and closer to the kind of it's becoming a meaningful lot of model (inaudible), but there's obviously still a big (inaudible), but also on revenue recognition between you and your partner. Number one, can you help us kind of understand the parameter here, and I think through what this might look like to moda kind of realized contribution in the P&L recognizing that it is (inaudible)?

And then second, in the Stage 1 monotherapy and combination study, can you just again help us understand a little bit about that Stage 1 prevalence of diagnosis relative to later stages? Cancer lung cancer is obviously relatively, compared to other cancers, age quite late. So it would be helpful to understand how you think about this market and potential building if we can see kind of some opportunities for those patients? And speaking of that opportunity, any comments on kind of what the bar looks like particularly compared to a watching and waiting scenario?

James Mock - *Moderna Inc - Chief Financial Officer*

Yes. Thanks, Courtney. I think we're breaking up a little bit, but I think the first question was around rev rec as it pertains to INT. So let me take that one. And I'll put a caveat out there that we don't even have the product approved. We're working with our auditors. It's not a traditional joint venture. So -- but this is -- I'll give you to the best of our knowledge, how we think it will work. So it will end up being that we deliver the product to Merck because they're obviously the market authorization holder, and they were sell it on to the customer. So that will be the first part of our transaction.

And so you can imagine some amount of our COGS plus some markup. Thereafter, whatever the profit split is, then we will take that share -- Our share of that of 50%. So it ends up being naturally somewhat greater than 50% of the profit share because it's predicated upon first shipping the product and having some markup on that and then taking the margin on top of that. So that will change over time because we -- as we've laid out before, we're working on our cost of goods sold and with that will continue to come down over time as we continue to drive automation. So it will start a little higher as our cost of goods sold.

Well, obviously, like any product starts higher and then get more productive over time. But that's the general framework, and I hope that helps. But again, we hope to be in that position next year to be able to start recognizing that revenue.

Stephen Hoge - *Moderna Inc - President*

(inaudible) cancer Stage 1. So lung cancer really represents a pretty unique opportunity because screening through X-rays has actually been an important intervention for identifying early-stage disease, Stage 1 disease. Now the majority of diagnoses still show up later at Stage 3, Stage 4, in particular, but you're seeing an increase almost a thitd, north of 30% of diagnoses are now earlier stage, Stage 1, Stage 2. And that has grown over the last decade and hopefully continues to grow through better screening, including a relatively easy intervention, a chest x-ray that your primary care doctor can provide.

So we do hope and expect that there's a big push on earlier -- catching lung cancer earlier. And that is a natural place, therefore, to try and intercept and intervene if you have a great benefit risk profile, again, to be proven, but we know we have the safety profile. And if we can do that, then we'll be able to dramatically impact the number of Stage 4 or Stage 3 and 4 diagnoses that start to show up.

You've already seen evidence of that, right? I mean if you look in the United States, over the last decade or two, there has been an increase in the number of diagnoses that have -- the percentage of diagnoses that are happening in earlier stage and a commensurate decrease that are happening in the later stages. And so we do think it's a unique tumor opportunity for us to go demonstrate Stage 1 intervention because of that screening regime around chest x-rays and the overall trajectory in the field.

Operator

Jeff Meacham, Citigroup.

Geoffrey Meacham - *Citi Infrastructure Investments LLC - Analyst*

I have two quick ones. The first one on Intismeran, as you grow the experience and data here, I know most of the trials are in combo with KEYTRUDA are there other I-O combo mechanisms that could also bear fruit, or is that better addressed with the rest of your oncology pipeline?

And the second one on norovirus. As we get closer to data, do you have any updated view of what success looks like here, just given the standard of care? My sense is a significant benefit is all you need, but want to get you guys' perspective?

Stephen Hoge - *Moderna Inc - President*

Yes. Thanks for both questions. So first, on the alternative IO-IO combinations, we are looking in the adjuvant setting and earlier in many of these Phase 3 studies. We do have a metastatic melanoma study, as you know. But we -- in that context, generally IO-IO combinations and the toxicity associate has not been seen as advantageous. And so for now, most of our focus is on the combination with the PD-1 and KEYTRUDA because of our partner, Merck.

We would be interested in subsequent studies in exploring alternative I/O combinations. But as you kind of alluded to, that's already something we're starting to do in the rest of our pipeline. And in particular, I'd point to 4359, where we are looking in metastatic melanoma and alternative regimens, CTLA-4 plus PD-1 combinations, EPI, Nivo as an example, have been important intervention showing benefits in those populations. And that's a place where, if we want to add a third I-O agent for hopefully some benefit, we are doing some early Phase 1/2 exploratory work right now.

So you might see, just as a function of the huge amount of work we're already doing in INT, you might see us first explore those other combinations for our cancer vaccines platform in the other off-the-shelf context first. But that doesn't rule out that in the future, we might explore the use of INT on top of other regimens. Certainly, both ourselves and our partner, Merck are interested in that.

Now on the norovirus side, I think you hit the nail on the head. We we think given that there is not currently an approved vaccine for norovirus, and given that particularly for those at highest risk, those over the age of 75, those that have other medical comorbidities, there really is a high societal and medical costs associated with the profound dehydration that can happen with even just what might feel like a two-day norovirus infection, not just hospitalization, but the significant exacerbations of underlying medical diseases as well and some death.

And so that population, anything that can be done to reduce that burden would be ultimately value creating for the health care system, put aside the benefits for the individual patient. And so we're -- we think statistical significance is the bar. Obviously, we want to see a vaccine efficacy that's also meaningful and so north of 50%. But on -- but given that there currently is no standard of care or treatment, we would take anything above there as a success.

Operator

Cory Kasimov, Evercore ISI.

Cory Kasimov - *Evercore Inc - Analyst*

I also have one on Intismeran. So wondering how critical is it to demonstrate an overall survival benefit in Interpath-001. Given the challenges of showing OS and adjuvant melanoma, do you believe physicians would interpret the data set any differently absent a clear OS signal?

Stephen Hoge - *Moderna Inc - President*

Yes. So I'd make a couple of observations. So first, RFS is a pretty good predictor. I mean this is a relapse-free survival. So again, it's not progression-free survival, it is survival, and tends to correlate. And if you look at our Phase 2 study, we have released previously the RFS, DMFS and even OS trend data. We look forward to the ASCO presentation to provide the five-year update and the view on RFS, DMFS and OS.

And I would point to that presentation and the data, and we hope that, that will provide confidence for physicians, for health care systems, for patients on that relationship in this case and in the case of Intismeran in combination with KEYTRUDA in the adjuvant melanoma setting, and that, that would provide sufficient confidence to move forward if the Phase 3 is positive.

Now the Phase 3 data, we will follow OS. And we're through five years in the Phase 2. So it will take us some time to get to that same level of data in the Phase 3, but it will be a part of the trials going forward and can provide a significant degree of confidence going forward, but again, RFS really is survival in this case.

Operator

Simon Bick, Rothschild & Co Redburn.

Simon Baker - *Redburn Partners LLP - Analyst*

Just looking at the Q2 revenues, a couple of quick questions. Firstly, should we -- or could you give us any color on the split? Or should we assume that the entirety is SPIKE vax? And also, Jamie, I wonder if you could give us any comments on phasing. It was a very strong number

against our expectations, but I just wanted to know if there was any pull-through of expected revenues from Q2, particularly with some of those governmental orders outside the US?

James Mock - *Moderna Inc - Chief Financial Officer*

Yes. Thanks, Simon. So let me address the first question. as it pertains to product split. This was largely, the majority is COVID still. So we have not been -- as we've always said, we don't anticipate RSV being a significant growth driver in the year 2026. We believe that will take a little bit of time for us. So this is still primarily COVID-related.

As for the timing, we laid out the second quarter. So -- and then I think maybe your question is more on the second half. But for the second quarter, we laid out $50 million to $100 million in the second quarter. So that should bring our first half to almost $0.5 billion of revenue. And that, if you look at that as probably $400 million outside the United States and $100 million in the United States.

So let me talk to the timing of the year and give big picture and kind of compare it to last year. Last year, we had $700 million of sales outside the United States, and it was $100 million in the first half and $600 million in the second half. So with $400 million is in the first half of this year, if we repeat last year, that's $1 billion. And we've been talking about saying that our mix between the US and international is going to be about a 50-50 split. So if we just repeat last year, that should get us $1 billion.

And then in the US last year was $1.2 billion. I said in my prepared remarks that we're expecting some amount of decline and we've modeled for that. So hopefully, that gives you a little bit of the phasing and timing here. And the last point I'll say is back to the question that was asked earlier, is in the second half of last year, we didn't have any UK revenue.

So to Stephane's point that if there is a fall season, in last year, $600 million outside of the United States. We did not have in the UK. There are other puts and takes that's why we've guided up to 10%. I'm not giving explicit guidance here, but I'm trying to give you the picture and contextualize what the year might look like from a US versus OUS split.

Operator

Andrew Tsai, Jefferies.

Andrew Tsai - *Jefferies LLC - Analyst*

It's a bigger picture question. I'm just curious what your guys' latest thoughts are on BD and even considering technology or assets beyond mRNA. Does it make sense to add more assets to your pipeline? Or do you think you're right sized for now?

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

Thanks for the question. So if you think about the company, as you know, we've always focused on building the most impactful mRNA platform to enable modalities, families of medicines to enable them a lot of medicines happening using the same technology components. We've done it with infectious vaccines. We don't it with Intismeran. I look at a number of studies now. We are doing it in rare disease.

And as we share more at our Science Day on June 25, we have been investing heavily to keep increasing in new modalities. You see it with a T cell engager that Stephen talked about (inaudible). You see it with 1439. And there's many more assets, we're going to walk you through what the science has enabled. So we're very focused on expanding to new modalities to enable new families of medicine.

As you've seen in the past, we acquired a company in Japan a couple of years ago because it was expanding the mRNA operating growth of Moderna. We are continuing to look at science across the board, whether it's from academic labs or from companies, public or private.

If we find the right opportunity to increase what we can do, we will, of course, execute on those priorities. But we don't have a pipeline problem like most companies in the industry. We have an abundance of products. As you know, we have been very disciplined on cost right now to get back to breakeven. But we have a lot of exciting science that is waiting to go into the clinic soon, and we'll share more of that on June 25.

Operator

Alexandria Hammond, Wolfe Research.

Alexandria Hammond - *Wolfe Research LLC - Equity Analyst*

So with the recent approval of the COVID flu vaccine in the EU, can you just walk us through your commercialization strategy? And I guess what is the successful launch of like a year from now and five years from now?

Stephen Hoge - *Moderna Inc - President*

Yes. Thank you for the question. So first, I want to start by saying, as is our pattern, our path, we do not expect revenues in the year of approval for these vaccines. And so 1083 (inaudible) or flu in the United States, none of those are in our guidance that Jamie was speaking about.

Now your question is more kind of looking forward in '27 and '28, what does success look like? The first step, the one we're engaging in right now across the major markets in Europe is securing market access and so that is pricing and reimbursement. That is a national process, and one that is underway, even publicly underway, for instance, in France, where they have initiated that, frankly, quite quickly after approval, which we think is an encouraging sign.

It's important to note that across Europe, there's about a $2 billion respiratory vaccine market. We previously sort of summarized that. Flu is a big part of that, and COVID is the second large part of that and it's much more portion reserve for RSV. So we see it as a very large opportunity for our combination COVID vaccine.

Lots of benefits to payers, to health care systems, to patients. Patients appreciate the -- it's only one shot and there's a strong preference on that. But payers and health care systems really appreciate the lower burden of work. It's a single product. It's only one injection. You don't have to procure both. And the amount of time you get back from a health care provider, be that a physician, a nurse, a pharmacist that they can get back to do other things that are value creating for the health care system is actually a huge part of the value proposition of the product.

And so what we've been doing with those governments, and we will do throughout the back half of this year, is help build that economic value story. We've got real-world effectiveness coming -- data coming out from our products, and we hope to be able to show their benefit for the individual, but we also want to help the health care systems understand and value the savings that they will get from a respiratory combination vaccine. And so that's the big push really over the next 12 months. We do hope for a successful launch in '27 in the first markets where we can get pricing and access. And in some cases, in Europe, that takes a couple of years as a process, and it would really be 2028 when you'd start to see that more significant uplift.

Our hope is that we end up with a very large share of that $1.8 billion to $2 billion respiratory vaccines market because we really do think we have a unique product that can save the health care system money and deliver better value for patients and providers. And so we're -- we'll have more guidance as we move forward. But rest assured that we are spending the next year securing that market access pricing and reimbursement and helping people understand the value of that combination. Patients get it quickly, health care systems are also getting it quickly, and we've got the work ahead of connecting those dots so that we can have a successful launch in '27 and really drive growth of the business in '28.

Operator

Thank you, ladies and gentlemen, this concludes the question-and-answer portion of today's program. I'd like to turn the call back to Stephane for any further remarks.

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

Well, thank you very much for joining us today. As you can see, we're excited about 2026, returning to sales growth and critical Phase 3 readouts norovirus, Intismeran and propylene acidemia. We look forward to talking to many of you over the next few days and a few weeks. We're excited to host you more from them Monday, June 1 at ASCO. And on June 25, Han Cambridge for a Science Day. Have a nice day, and have a great weekend.

Operator

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