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MRNA.OQ - Q4 2025 Moderna Inc Earnings Call

EVENT DATE/TIME: FEBRUARY 13, 2026 / 1:00PM GMT

OVERVIEW:

Company Summary

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PRESENTATION

Operator

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

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

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

Thank you, Kevin. Good morning, everyone, and thank you for joining us on today's call to discuss Moderna's fourth quarter 2025 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 Investors section of our website.

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

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

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

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

Thank you, Lavina. Good morning or good afternoon, everyone. Thank you for joining us. I will start with a quick review of 2025, Jamie will present our financial results and 2016 outlook, Stephen will review our commercial outlook and clinical programs, and then I will come back and share our key value drivers as we look ahead before we take your questions.

Let me start with a review of '25. Our revenues were $1.9 billion, driven by sales of our COVID vaccines, Spikevax and mNEXSPIKE. We continue to make tremendous progress on costs in 2025. Operating expenses were down $2.2 billion or 30% for the year. I would like to thank the entire Moderna team for this great accomplishment in 2025. I'm very proud of this.

Net loss for the year was $2.8 billion, and we ended the year with $8.1 billion in cash and investments. Before I start a review of 2025, I want to express all this appointment to the FDA, who will be able to file later on our full program, mRNA-1010. The current uncertainty in the US FDA regulatory environment creates real challenges for businesses, patients and the broader innovation ecosystem.

When expectations and review time lines are unpredictable, companies face greater risk and can hesitate to invest, slowing the development of breakthrough medicines. This delays patient access and increases overall health care costs. Sustained regulatory uncertainty frightens US leadership in innovative medicines.

This can also result in transformative medicine developed by US companies becoming available to patients outside the US before reaching American patients. Turning now to the execution on commercial and pipeline.

On the commercial side, in 2025, we have three products on the market, Spikevax, mNEXSPIKE, mRESVIA. Spikevax was approved in the US in 2025. It has an excellent launch, quickly became our leading product in the US. In the past 2 weeks, we announced two commercial agreements. First, an agreement with record at for the global commercialization of our propionic acidemia rare disease candidate, currently in the pivotal study.

We call that he brings deep rare disease commercial expertise and an established global infrastructure with a prophetic acidemia community. We also announced earlier this week a 5-year strategic agreement with the government of Mexico for respiratory vaccine supply. We currently have two products under regulatory review in multiple countries. Our seasonal flu vaccine is filed another review in Europe, Canada and Australia.

Our flu plus COVID combination vaccine is filed and under review in Europe and Canada. Additionally, we made strong programs across the pipeline. For [Intiburan], our individuals cancer therapy developed in partnership with Merck, we recently reported positive 5-year Phase 2 data in adjuvant melanoma, demonstrating the durability of clinical benefit, and we are foreseeing our confidence in the program's long-term potential.

I am very happy to announce that we have completed enrollment in our Phase 2 study in muscle-invasive bladder cancer. This marks fully stage studies in three different cancer tacks that are now fully enrolled adjuvant melanoma, adjuvant renal cell carcinoma and now muscle-invasive bladder cancer. We look forward to the data with us from these studies.

For cancer antigen therapy, mRNA-4359, we announced positive Phase 1b data and the promise now in Phase 2. Our Phase 3 novirus program is now fully enrolled, so we could see Phase 3 data in 2026. In our peer program is still fully enrolled in this retraction study and with UTC data in 2026.

I am free to welcome to Modena, our new Chief Development Officer and Executive Committee member, Dr. David Berman. He has contributed to the development of more than 1,000 clinical stage immunotherapies at BMS and AstraZeneca. His expertise will serve Moderna well as we continue to expand our oncology pipeline.

David served most recently as Head of R&D of Immunocore. We very much look forward to David joining Moderna's team on March 2. I work, of course, to take this opportunity to thank Jackie Miller for her many contributions in over the last 5 years of the company, especially a tremendous leadership during the pandemic.

With this, I would like to take over to Jamie.

James Mock - *Moderna Inc - Chief Financial Officer*

Thanks, Stephane, and hello, everyone. Today, I'll cover our fourth quarter and full year 2025 results and then wrap up with our 2026 financial framework. I'll begin with our 2025 revenue performance on Slide 8.

For the fourth quarter, total revenue was $700 million, coming in at the higher end of our recent guidance. Our revenue split in the quarter was $300 million in the US and $400 million from international markets. For the full year, total revenue was $1.9 billion, with the majority generated from COVID vaccine sales, along with approximately $100 million of other revenue.

From a geographic perspective, US revenue totaled $1.2 billion, while international revenue was $700 million. In the US, while overall COVID market demand declined year-over-year, we had strong market share in the retail channel, supported by the successful launch of mNEXSPIKE. In international markets, we landed at the higher end of our range, driven by operational performance and vaccination rates, which were above or in line with our expectations.

Turning to Slide 9, I'll review our fourth quarter results. As we discussed on the prior slide, revenue was $700 million. Compared to the fourth quarter of last year, operating expenses were down 31%, reflecting continued cost discipline and execution across the organization. I'll discuss these expense trends from a full year perspective on the next slide.

Our net loss for the quarter was $800 million compared to a net loss of $1.1 billion in the fourth quarter of 2024. Loss per share was $2.11 compared to a loss per share of $2.91 last year. Now turning to Slide 10. I'll walk through our full year 2025 financial results. As I mentioned earlier, total revenue was $1.9 billion.

Cost of sales was $868 million, representing a 41% decrease compared to 2024, primarily driven by productivity and lower inventory write-downs, contract manufacturing wind down costs and sales volumes. R&D expenses were $3.1 billion, representing a 31% decrease compared to 2024, driven by continued investment prioritization and efficiency gains in the execution of our clinical trials.

These reductions were partially offset by increased investment in our neuro virus vaccine and oncology programs. SG&A expenses were $1 billion, representing a 13% decrease compared to 2024. The decline was driven across all functions, and reflect our continued focus on operating efficiently while supporting the business in a disciplined manner.

Our income tax provision for 2025 was immaterial. We continue to maintain a global valuation allowance against the majority of our deferred tax assets which limits our ability to recognize tax benefits from losses. Net loss for the full year was $2.8 billion compared to a net loss of $3.6 billion in 2024.

Loss per share was $7.26 compared to a loss per share of $9.28 last year. We ended 2025 with cash and investments of $8.1 billion, compared to $9.5 billion at the end of 2024. The year-over-year decrease was primarily driven by operating losses as we continue to invest in R&D and advance our pipeline, partially offset by the $600 million initial draw of our $1.5 billion credit facility.

Excluding the credit facility draw, we would have ended the year with $7.6 billion of cash and investments, which was above our 3Q guidance of $6.5 billion to $7 billion due to lower operating expenses, lower capital expenditures and working capital improvements. Now let's turn to our financial framework for 2026.

We expect total revenue growth of up to 10% in 2026. This growth is expected to come primarily from international markets, and we estimate our geographic mix will be well balanced between the US and markets outside the US in 2026. This is a shift from our 2025 revenue split of approximately 62% US and 38% international.

We will begin selling locally manufactured products in both the UK and Australia in 2026, which is the largest driver of our international growth. Our 2026 revenue guidance factors in future potential declines in COVID vaccination rates and also assumes no revenue from our flu vaccine or our flu/COVID combination vaccine.

Similar to 2025, we expect 2026 revenue to be weighted to the second half of the year, with approximately 15% of our revenue in the first half and approximately 85% in the second half. Cost of sales is projected to be approximately $900 million. While this is flat year-over-year in absolute terms, we are expecting gross margin rate improvement from manufacturing efficiency gains and volume leverage.

R&D expenses are anticipated to be approximately $3 billion as we continue to invest in our late-stage pipeline while maintaining financial discipline. It's a relatively small decline from the $3.1 billion we had in 2025 due to the continued execution of our late stage trials in infectious disease.

For modeling purposes, we expect our R&D spend to be relatively balanced in the first half versus the second half of 2026, similar to what we experienced in 2025. SG&A expenses are expected to be approximately $1 billion, flat versus the prior year. We remain focused on driving efficiency and cost savings across the organization, which we will use to fund new commercial investments to support both geographic expansion and future product launches.

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, we are expecting total GAAP operating expenses of $4.9 billion and $4.2 billion of cash costs, which excludes stock-based compensation, depreciation and amortization.

We expect taxes to be negligible in 2026. Capital expenditures are projected to be between $200 million and $300 million. This guidance includes our previously announced investment in building our own fill/finish capacity in the United States at our existing site in Norwood, Massachusetts. We expect to end 2026 with $5.5 billion to $6 billion of cash and investments. Our cash guidance does not assume any additional drawdown from our credit facility.

In summary, 2025 was a key turning point in our financial story. We improved our commercial execution, exceeded our cost reduction plan by over $1 billion and ended the year with over $2 billion more cash than our original 2025 guidance, all while still advancing our pipeline.

I want to thank the entire Moderna team for their efforts over this past year, and we have strong momentum heading into 2026, with multiple levers for revenue growth and a strong commitment to drive additional cost reductions across the company.

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

Stephen Hoge - *Moderna Inc - President*

Thank you, Jamie, and good morning or good afternoon, everyone. Today, I will review our commercial outlook as well as progress across our pipeline. As Jamie mentioned earlier, we expect 2026 to mark a return to revenue growth for Moderna.

This year, we expect growth to be driven primarily by our strategic partnerships and the second year of launch for mNEXSPIKE, which I will discuss in more detail in a moment. But first, looking forward to 2027, we see three additional growth drivers.

We look forward to significant expansion of our addressable market with the opening of the $1.8 billion European respiratory vaccines market. As a reminder, we have been excluded from this region for several years due to a competitor pandemic contract, which expires in 2026.

We expect to launch mNEXSPIKE, our stand-alone flu vaccine mRNA-1010 and our combination flu/COVID vaccine in the European region by 2027 winter season. adding to mRESVIA and mNEXSPIKE, which are already approved. This broad portfolio represents the opportunity to grow our share in the large European market, which will contribute to meaningful revenue growth from 2027 forward.

Second, we expect growth from our new multi-year strategic agreements in Latin America and Asia Pacific. And third, with the acceptance of our flu filings in Europe, Canada and Australia, we anticipate that our flu vaccine will begin to contribute to revenue internationally.

In 2028, we expect continued new product-driven growth opportunities with both our combination flu/COVID and norovirus vaccines potentially being launched across many of our markets. Recent execution supports this growth strategy with approvals for mNEXSPIKE in Canada and Australia, and the approval of our strain updated Spikevax co-vaccine in the UK.

We have already shown strong momentum against the 2027 growth drivers. We announced a multi-year strategic agreement with Mexico earlier this week and Taiwan last month and we continue to make progress under our previously announced strategic agreement in Brazil.

Finally, although not a major driver, we also signed a global commercialization collaboration in PA with (inaudible) as we prepare that potential launch in 2028. The UK is both -- let's take a closer look at the key contributors to that growth in 2026, beginning with our strategic partnerships with the UK, Canada and Australia.

As a reminder, these are long-term agreements, under which Moderna has built local manufacturing sites and committed to ongoing domestic research and development. These partnerships are core to each country's national security and public health strategy, strengthening preparedness against current viruses and future pandemic threats.

The UK is the largest of these markets, and we expect a $200 million UK COVID order to be fulfilled in the first half of 2026 for their spring booster campaign. We also expect to supply vaccines for the UK's fall vaccination campaign, initially this year for COVID, with the potential to expand to other respiratory vaccines such as flu, RSV and our combination vaccine in the years ahead.

In Canada, we are thrilled to deliver a -- we were thrilled to deliver made in Canada COVID vaccines in 2025 and expect to see the full annualized impact of the agreement in 2026. And in Australia, we expect to deliver the full annualized benefit of our agreement in 2026 as well.

Moving to Slide 15. Our second major expected growth driver in 2026 is our new COVID vaccine, mNEXSPIKE. mNEXSPIKE had a very successful launch in 2025. This is especially notable because mNEXSPIKE was approved mid-year in '25 and was only available commercially in the United States. We are extremely pleased with the market share achieved in that first season with them mNEXSPIKE capturing 24% of the total US retail market and 34% of the retail market among adults aged 65 and older.

As a reminder, the retail market is the largest customer segment, representing approximately 3/4 of the U.S. COVID market, and the majority of that volume is in seniors. Looking ahead to 2026, we expect to continue to drive the uptake of mNEXSPIKE in the United States.

And internationally, we look forward to approvals and launches in multiple countries this year and the years to come. Moving to Slide 16, which -- this outlines the latest developments in our infectious disease portfolio. Starting with our approved products. The updated formulation of Spikevax is approved in countries around the world.

And importantly, in 2025, we received the supplemental BLA approval in the United States for high-risk children as young as 6 months. As mentioned earlier, mNEXSPIKE was approved and launched in the US. It was approved in Canada in 2025 and recently approved in Australia as well.

We are targeting further approvals in -- of mNEXSPIKE in Europe, Japan and Taiwan this year. mRESVIA, our RSV vaccine has been approved for adult age 60 and older in 40 countries and approved for high-risk adults, age 18 to 59 in 31 of those 40 countries.

In addition to those three approved vaccines, we filed for two additional approvals mRNA-1010, our flu vaccine has been accepted for review in Europe, Canada and Australia with the first potential approvals coming late in '26 or early '27.

We were disappointed with the FDA's refusal to file letter for mRNA-1010 and have requested a Type A meeting to understand the path forward for the program in the United States, mRNA-1083, our flu plus COVID combination vaccine is under review in Europe and Canada, with first potential approvals in 2026.

And finally, our norovirus vaccine is in an ongoing Phase 3 trial, which is fully enrolled in its second Northern Hemisphere season and is accruing cases towards its interim analysis. Now turning to our therapeutics pipeline [Intisarin], our individualized cancer therapy developed in collaboration with Merck has a total of 8 Phase 2 or Phase 3 studies ongoing.

The most advanced of these is our Phase 3 adjuvant melanoma study as well as our Phase 2 randomized adjuvant renal cell carcinoma study, both of which have been previously announced as fully enrolled. As Stephane mentioned previously, we are very excited to announce that we have now fully enrolled our Phase 2 randomized muscle invasive bladder cancer study. Bladder cancer is the third cancer type now in a fully enrolled late-stage study.

In addition to these 3 trials, we are looking forward to completing enrollment in our ongoing Phase 3 studies in adjuvant non-small cell lung cancer. We also look forward to completing enrollment in our ongoing Phase 2 trials in non-muscle invasive bladder cancer, first-line metastatic melanoma and first-line metastatic squamous non-small cell lung cancer.

Beyond these Phase 2 and Phase 3 studies, we are fully enrolled in our Phase 1 studies for adjuvant pancreatic cancer and perioperative gastric cancer. And we look forward to data from these studies in the year ahead.

Aside from -- aside from our collaboration and Intisarin with Merck, we continue to make progress in additional oncology programs. In the Phase 2 study of our cancer antigen therapy, mRNA-4359, cohorts are enrolling in first-line metastatic melanoma, second-line metastatic melanoma and first-line metastatic non-small cell lung cancer.

In mRNA-2808, our T-cell engager in multiple myeloma, we are dosing in our Phase 1/2 study. We're also dosing in the Phase 1 study of our cancer antigen therapy mRNA-4106. And rounding out our early-stage oncology programs, our Phase 1 study is also dosing in our cell therapy enhancing program, mRNA-4203, in collaboration with [Ematic]. In rare diseases, our proprionic academia or PA program is fully enrolled in its registrational study. And in methylmalonic acidemia, or MMA, we expect our registrational study to start in 2026.

With that, I'll hand the call back over to Stephane.

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

Thank you, Stephen and Jamie. Looking ahead, we see multiple commercial, pipeline and financial value drivers that will move Moderna forward in 2026. Commercially, we believe the market share gains from mNEXSPIKE will continue in 2026 and beyond. We will also benefit from a full year contribution from our strategic partnership in the UK, Canada and Australia.

That will be an important growth driver for Moderna in 2026. And we expect up to 10% revenue growth in 2016. From a pipeline standpoint, we look forward to potential regulatory approval of mNEXSPIKE in Europe, in Japan and in Taiwan. We also expect potential approval of our combination flu plus COVID vaccine in Europe and Canada, where regulatory filings are under review. In the US, we plan to refile planning further guidance from the FDA. For seasonal flu vaccine, we look forward to an approval in Canada this year.

This is going to be an important year for oncology patients and for Moderna. We also expect continued clinical momentum from our [Intismal] program, as Stephen just described. Last month, we reported positive 5-year Phase 2 data in adjuvant melanoma. Potential clinical milestones from the [intestinal] program include Phase 3 adverse melanoma data, Phase 2 adjuvant renal cell carcinoma data and Phase 1 data in adjuvant pancreatic and perioperative gastric cancers, all of which have been fully enrolled for quite some time.

We also look forward to a Phase 2 result for our cancer antigen therapy mRNA-4459, the Phase 2 results for norovirus and the pivotal data readout from our PA program. That will be a busy year. From a financial standpoint, teams across the company continue to make progress on cost discipline, and we expect cash costs to decline approximately to $4.2 billion in the year.

As part of our cost efficiency program, the adoption of AI tools as such every part of our business, and we expect further productivity improvement in 2026. Moderna has a strong momentum as we head into 2026. We are poised to deliver up to 10% revenue growth as we continue to reduce costs. We expect to see approvals of infectious vaccine that will expand our commercial portfolio.

And we foresee multiple potential clinical data catalyst, driven by our latest oncology programs in rare disease and infectious disease. In closing, I want to recognize the entire Moderna team for their relentless drive. Our progress, clinical, commercial, operational, is dedicated to one mission, delivering the greatest possible impact to people through mRNA medicine.

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

QUESTIONS AND ANSWERS

Operator

Thank you ladies and gentlemen. (Operator Instructions)

Terence Flynn, Morgan Stanley.

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

Hi, thanks so much for taking the question. I had two parts. I guess the first one is just on the flu RTF implications for the 2028 cash flow breakeven guidance? And then timing of the Type A meeting like when you might get some visibility on next steps?

And then the INT program in adjuvant melanoma. I know that's a very important program and catalyst for the company. And so can you refine at all the timing of that data, whether it's going to be first half or second half?

Thank you so much.

Stephen Hoge - *Moderna Inc - President*

Sure. Maybe I'll take the questions on regulatory first, and then, Jamie, hand it over to you on any breakeven implications. So we're actually very pleased that the flu file is under review now in Europe, Canada, Australia. We'll be filing in additional countries this year. And all of that is with an eye towards having that start to contribute, as I said a moment ago, in 2027, in the fall of 2027 to our growth.

We also are pleased that the flu/COVID combination product remains under review and making progress in Europe for this year. As it relates to the US timing, it really -- we need to engage with the FDA in the Type A meeting, that's usually 30 days as a process, and understand from them what is going to be required to get that product moving forward in the US.

We absolutely feel that American seniors should have access to the same innovations. We do think this year, in particular, where there's a potential for a mismatch in one of the strains, it's particularly important that technologies like Moderna's mRNA platform are used to advance new and potentially improved products.

But at this point, until we have that Type A meeting, we won't really know how quickly we can get moving forward with the 1010 file in the US as we've been doing outside the US Jamie?

James Mock - *Moderna Inc - Chief Financial Officer*

Yeah. Terence, thanks for the question. I appreciate it, and I recognize that it's on investors' minds. As Stephen just said, though, this is a bit of a fresh and fluid situation. And without understanding the resolution of what is next for our flu product, it's a little bit difficult to comment at this time.

But here's what I would say. If you go back to the growth drivers we laid out at Analyst Day as well as Stephen had in his prepared remarks, we have 10 large shots on goal to increase revenue over the coming years, all with a wide range of potential outcomes. And Stephen mentioned some of the progress. We announced our long-term partnerships with Mexico and Taiwan.

We're excited about -- as I said, we're excited to deliver for the UK and Australia this year, which will be substantial revenue growth. mNEXSPIKE had a great first year. We're excited about the second year, both in the US and outside the United States. We're looking forward to Europe opening up.

So it's really -- there's still so many scenarios that could happen here, Terence, that it's a little bit too early to tell. On top of that, we have a ton of momentum on productivity and what we're doing from a cost perspective. So we're really excited about our financial profile.

We ended the year with over $8 billion in cash. We have a ton of momentum from a cost perspective, and we have a lot of opportunities for growth. So at this point, without knowing resolution to what's going to happen on flu, I think it's a little too early to tell.

Stephen Hoge - *Moderna Inc - President*

And on INT, the second question. We we don't have, obviously, more specific guidance than we previously put out there. I'd highlight, as I said a moment ago, that there are 5 histologies now under review or under different stages of clinical development. So INT for melanoma, the adjuvant melanoma study is 1 that we are confident will read out this year. It is an event-driven trial, and so it will depend upon the accrual of those events.

We have RCC, renal cell and bladder are now fully enrolled. And again, those are going to be event-driven and milestone-driven readouts. And so it's possible. And then the Phase 1 data that we referenced before for our peri-adjuvant gastric and adjuvant pancreatic monotherapy cohort. And so it's going to be a busy year for us over the next number of months. But we don't have more specific guidance because some of the most important readouts are ultimately event-driven.

Operator

Salveen Richter, Goldman Sachs.

Salveen Richter - *Goldman Sachs Group Inc - Analyst*

Good morning. Thank you for taking our question. This is Elizabeth on for Salveen. We wanted to ask about the flu and COVID combination vaccine and just given the RTF for 1010, how should we think about this refiling? And is there any read through from a regulatory standpoint in the US?

And then maybe just remind us of the study data that went into the submission initially and with the latest thinking is on what might be needed to be added for refiling? And then a second question on an wanted your thoughts on which of those 5 histologies you just mentioned have the highest probability of success kind of based on the read through from data generated to date?

Thank you so much.

Stephen Hoge - *Moderna Inc - President*

Thanks for both questions. So first, on the 1083 file, again, I'll underscore that we're hoping for approval of the flu/COVID combination product in Europe first in the this year. And so we'll move forward there. As it relates to the US, we were holding back on refiling the combo vaccine until we completed some portion of the review of the flu vaccine.

With the refusal to start the review of the flu vaccine, I think that is now gated on, again, the feedback from the Type A meeting, which we haven't had about what more would be necessary for us to refile for the mRNA-1010 program.

And then we would be able to provide more clarity on the flu/COVID program and refiling there, again, all of this in the US because all of those files are moving forward internationally. You asked about the data that was in the file. We had a Phase 3 study for the mRNA-1010 file, which we have previously presented the results on.

And actually, it's out for a peer-reviewed publication right now. But really excited by that Phase 3 study, which is a randomized 41,000 person study that we had agreed with the FDA and agencies around the world with prior to initiation. In that study, as a reminder, we saw 27% superior relative vaccine efficacy compared to the standard dose control.

And just to give you a sense of where that stands relative to comparators, the two of the licensed preferentially recommended vaccines for those over the age of 65, had run essentially the same study design, one of them even with exactly the same comparator. And those, if you look at the USPI for Fluzone, they had seen 24% relative vaccine efficacy for flu block.

If you look in their USP IOC, 30% relative vaccine efficacy. So at 27%, we felt very good that we were in line in demonstrating superiority in exactly the same way that those standard of cares have in the same population as over the age of 65.

We also ran a Phase 3 study, an immunogenicity and safety study, comparing our vaccine candidate for flu against flu zone high dose. And in that case, we showed statistical superiority to flu zone high dose on immunogenicity. That study has been published in the journal of Vaccine, and is available, I think, on our website for those who are interested in. So that package was in the initial file. We think it's a very comprehensive data set.

We do think if we can get the review initiated, it will support the use of the product. But we do need to understand first from FDA in that Type A meeting what they would need to initiate the review of the file that they previously had agreed to review.

Moving to entismarin. I think it's obvious that you ask where we see the highest probably success. It's hard to argue with the Phase 2b results that we have for adjuvant melanoma. As we announced last month, the 5-year survival data continues to look really strong, approximately a 50% reduction in the rates of relapse or death from melanoma, real stability in those curves through now 5 years.

And if you ask me, where do I think the read-through of that is, I think it's clearly, we hope, into the Phase 3 adjuvant melanoma study that is testing in largely the same population and exactly the same standard of care.

I think if it works, if we see that there, one of the reasons we and our partner, Merck, went in with renal cell and and bladder was we thought muscle-invasive urothelial cell carcinoma is -- we thought those would be places where we might also see relatively quick read-through. And so I hope that those also have positive readouts. But I think if you're asking where we think the probably success is highest, it's clearly in the -- it's in the Phase 3 adjuvant melanoma.

Operator

Eliana Merle, Barclays.

Eliana Merle - *Barclays - Analyst*

Hey guys, thanks for taking the question. Just can you elaborate a little bit on how you're thinking about the European COVID vaccination market, and how you see the vaccination rate and pricing evolving there? And also how, outside of the US, you're thinking about the pathway for potential flu/COVID combination vaccine approval?

And then also on that topic around flu, just in your filings for flu in Europe and Canada, has there been any discussion around potential strain selection in the future and potentially selecting the strains closer to the season start?

Thanks.

Stephen Hoge - *Moderna Inc - President*

Yeah. Thank you for all three. So first, I'll take the combination question. So -- actually, the COVID question. So mNEXSPIKE is moving forward with approvals internationally, and we're really pleased with the profile of that product.

As I'll remind you, we had demonstrated in that Phase 3 study higher relative vaccine efficacy. In fact, in a post hoc analysis, very high, approximately 25% higher relative vaccine efficacy compared to mNEXSPIKE in older adults with comorbidities. And so I really do think it's got a strong profile as the European COVID market reopens.

Now as to pricing, we haven't issued that yet, but we do believe that the current market is, as we've shared, approximately $700 million today. And that doesn't account for wastage that exists in the market. There are many doses that are being -- more doses that are being purchased under that dynamic contracts that are not getting used. That estimate of approximately $700 million is just what we see as shots in arms.

So we do believe that market will be larger than that -- larger than even if we see nothing more than the approximately 20 million shots in arms that currently are happening, and we do hope to get a sizable share. We think mNEXSPIKE will be a very competitive product profile in that market, and we're scaling up for that launch.

As you know, Europe is not one market, it is a series of different markets and some places we'll compete traditionally with sales and market activities. Other markets are more tender-driven, and we're preparing for all of that activities really starting this year, but as we said, as a meaningful driver of growth in '27 and beyond.

On the combination product, we actually think that's the next step in that strategy. We're very pleased by the combo products progress in its international reviews. As we've said, based on timing, we do expect a European review to move forward, and we are hoping for approval this year, which gives us a chance to launch as early as this year, more likely in '27, again, it just depends on timing of these events because proximity to the season will make a launch very difficult.

But it is clearly a great opportunity for us to move beyond just COVID into a combination product and an opportunity to both expand our share in the COVID space, but also grab share in the flu space. And we are proceeding with the filings elsewhere. I think we referenced in the PR Canada for that combination product as well and hope to similarly bring forward that innovation because we believe there's strong demand from health systems as well as patients for 1 shot or 1 vaccine that does multiple things.

Now as it relates to the flu, we have been having those conversations. So mRNA-1010, as we've proceeded outside of the US, there has been strong appetite for the question of better strain matching. And in fact, in some public comments, you've seen some European regulators, but also some from other markets. Vocally advocate for later strain selection and more diverse strain selections happening in flu vaccines, because of the precedent we've shown with COVID vaccines.

I'll remind you that in -- we sometimes forget in the US, but in this country, we've actually -- the FDA has chosen different strains of COVID vaccine than the rest of the world in two out of the four past seasons. And the data has shown that, that better matching for the market has led to slightly better efficacy. In fact, we ran a clinical trial once head-to-head back in the bivalent days and showed higher point estimates for efficacy, which makes sense, better match vaccines, you would expect to be better at protecting people.

And what we're hearing from the international flu community, including, as I said, in Europe, is quite strong support for that. It's a real question today. I mean, just to make the point, there is a -- there are a couple of different strains of [influenza B] circulating around the world right now. In the United States, it is a different strain than is circulating in the rest of the Northern Hemisphere.

And there doesn't look like there would be great cross protection. And so it just highlights that the right answer for this fall could be very different from a composition perspective for Europe or North America or other regions. And that's where the technology that we have that has allowed us to tailor and meet regional needs with COVID, we think, can have an impact. There are many other things we need to do to improve flu vaccines, but this is one we can -- we know we can do right now.

Operator

Tyler Van Buren, TD Cowen

Greg Wiessner - *TD Cowen - Analyst*

Hey, good morning. This is Greg on for Tyler from TD Cowen. So some investors have been surprised by the higher than-expected cash balance at year-end. So can you explain why that occurred and what the additional levers to lower cash costs are moving forward?

Thanks.

James Mock - *Moderna Inc - Chief Financial Officer*

Yes. Sure, Greg. Maybe I'll just go back to our original guidance. So when we laid out our original guidance, we said $1.5 billion to $2.5 billion of revenue. So $2 billion at the midpoint. And we said $5.5 billion of cash costs. So if you take those two together, it's a $3.5 billion usage from a starting point of $9.5 billion, which is why we guided $6 billion.

Since then, revenue essentially came in online. We had [$1.944 billion] let's call that pretty close, cash cost came in at $4.3 million. So we beat by $1.2 billion. On top of that, we took $600 million of the initial drop from the loan, so that's now $1.8 billion better. Our capital expenditures were $100 million less than we forecasted at the outset of the year, so that's $1.9 billion better.

And then if you look at the working capital, I am really pleased. It doesn't get a lot of attention with how the team has performed. Our receivables are at $180 million. Inventory was flat year-over-year at $270 million, payables at $300 million. We have a net working capital balance of $150 million to which we run this company on.

And that is really incredible performance from the team, and that drove the last $200 million. So I don't think it should be too much of a surprise that it's mostly cash cost for $1.2 billion above our original guidance, the loan, little bit less capital expenditures and then terrific performance on working capital from the team.

Operator

Michael Yee, UBS

Michael Yee - *UBS AG - Analyst*

Great, thanks. We had two questions as well. First, on the adjuvant Phase 3 melanoma study. Can you remind us that, that study has interims built in and then, of course, a final, and so like other design studies you've done, there's a certain number of cases you crew, you take a look at it and then if it doesn't stop, you move to the next case next interim, can you just describe a little bit of how that works and remind us the Phase 2, I think, did stop at an interim, if I was correct there.

And then on norovirus, I don't think anyone's asked on that, but can you just remind us there you are enrolling or expect to complete enrollment and then there's actually a readout, I think, planned this year. What is your confidence level there? I know there's been a lot of disappointments previously, but I think you are targeting a different approach and using three different strains, which I think I assume you believe will capture the majority of coverage. Can you just remind us there and how you think about that result?

Stephen Hoge - *Moderna Inc - President*

Yeah. Thanks, Mike, for both questions. So first on the INT Phase 3 for adjuvant melanoma, you're correct. It's the first analysis that we'll see this year will be an interim analysis, looking at our primary endpoint of relapse-free survival. We have a number of additional analysis.

If that -- if you get there and we don't have the statistical power to declare early success then, then we would move forward to subsequent analyses and ultimately, additional endpoints, including things like just a metastases-free survival. What I'd remind you is the Phase 2 hit essentially a statistical hypothesis at the interim.

And then what we've been following since are the others. And we believe we've conservatively designed this study so that if those results are repeated, we would be well powered to see that in this first interim. But if for whatever reason, we're told to continue forward, there would be a subsequent analysis.

And that, again, will be event-driven, but presumably would come the year after. As to the norovirus study, we are very excited to see those results potentially this year, again, a case-driven trial. As you highlighted, there had been some previous efforts in norovirus. Ours are quite different.

So first, the composition of our vaccine, as you highlighted, is a trivalent here, and we are looking at strain-matched efficacy, which is important because it does allow us to make sure that we're looking at the performance of the vaccine, which is matched at strains that are in approximately in most years, two/three to 70% of the circulating norovirus disease.

And so that trivalent composition and the VLPs that our technology make, we think, is a differentiator. But perhaps the more important one relative to the trial, I think you were referencing is we're looking in seropositive populations, not children.

And so earlier studies that have struggled in norovirus have looked at in children in primary vaccination often a couple of doses as opposed to really where the burden of disease is as you become an adult is in older adults, those particularly over the age of 65, where the threat of really profound dehydration can lead to hospitalization and complications of a whole number of medical comorbidities.

And so there's a actually even bigger need in that population. And in that case, it's more of a booster trial. It's much more like -- it's a bit like primary vaccination for whatever it is, RSV or flu or COVID, being very, very different than boosting seropositive people so that they can protect, which is a lot more like what you see with our senior flu, COVID and RSV vaccines, which have obviously been successful.

Norovirus is a different one, but we do believe that, that difference in population will make a difference in terms of the ability of a vaccine to help protect them against this disease.

Michael Yee - *UBS AG - Analyst*

Thank you. And as a follow-up, do you think that the guidance with FDA or the discussion or regulatory path for this would be very different for an put another way, much more obvious than perhaps what's going on with?

Stephen Hoge - *Moderna Inc - President*

So look, Michael, I'd remind that we have -- we got three products approved last year in the US or some label expansions, RSV and a new COVID product and a pediatric COVID. And in those cases, the guidance was different. What we're experiencing with flu is, I think we hope flu specific. Our norovirus study, to your point, is a very large placebo-controlled study.

And so the Type A -- the refusal file letter that we have received from the FDA on flu really speaks to a change in their perspective on the comparator used. But in the case of norovirus, there is no comparator to use. And so the comparator in that clinical trial is placebo. If we're able to demonstrate efficacy over placebo, it's hard to argue that there's a problem with the comparator.

Operator

Luca Issi, RBC Capital Markets.

Unidentified Participant

Great. Hi, team. This is [Shelby] on for Luca. Maybe on IMT. congrats on the recent 5-year data for melanoma, and it's great to see the hazard ratio for RSS is remaining consistent with prior cuts. However, what about OS? I remember at ASCO in 2024, you said some pretty compelling data with the initial separation of the curves, but the press release this time was silent on OS.

How should we read that? Does that mean the OS curves are no longer separated? Or are you just keeping the details or maybe an upcoming medical meeting? Any color there? Much appreciate it.

Thanks.

Stephen Hoge - *Moderna Inc - President*

Yeah. Let me say it this way. We look forward to sharing the OS curves at an upcoming medical meeting. We -- where you see relapse-free survival holding obviously, included in relapse-free survival is survival. And so we obviously didn't put that out because we want to make sure that we're able to bring that forward to the community in a place where they can see all of that data, but all data from the 5-year interim analysis will be presented at an upcoming medical meeting. Until then, I really shouldn't say more.

Operator

Thank you. Courtney Breen, Bernstein.

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

Hi, thanks so much for taking our question today. Just a couple in building off the conversation around the ITS that you got for the flu 1010. With bench defined kind of an immunogenicity sub-study. I think of that Phase 3 efficacy study, which suggested -- and it was a very small population of that study suggested there was a 50-50 ratio between those under and over 65.

Can you just remind us or share with us what percentage of patients in that efficacy study were 65 or older? And then additionally, as we think about kind of INT and the path to approval and kind of -- have you had any feedback in the design of that clinical trial that perhaps provided some recommendations that weren't followed.

Additionally, kind of will it be you or Merck taking that file forward? And kind of can we assume that CIBA will be the FDA group that will assess that particular file?

Thank you so much.

Stephen Hoge - *Moderna Inc - President*

Yeah. Thank you for the questions. So first on the Phase 3 trial design for our flu vaccine. You're correct, and your memory is right. More than 50% of the population of the study was stratified that at least 50% would be over the age of 65.

We also had a very large population, north of 10%, that was above the age of 75. And as we have presented at medical meetings and will be available in the upcoming publication, we've seen really strong superior efficacy across all of those populations. In fact, it's remarkably consistent.

And as you add frailty or other risk factors to age, or as you look to severe outcomes such as hospitalization, you'll see those point estimates for superiority go even higher, and in many cases, become even more statistically significant.

So we feel very good about that 41,000-person study which, as you just described, or as I just said, has more than 20,000 people over the age of 65 in it. I did describe a separate Phase 3 study just to avoid confusion, the P303 study Part C. That has 3,000 people in it, and that was the study that was head-to-head against Fluzone high dose that showed superior immunogenicity. But the efficacy study, I think, was the one that you were asking about.

Now as it relates to INT, INT is -- we're moving forward in a very novel field. And so we've had robust and I would say, highly productive engagement with the FDA and truly global regulators around the -- what will be a first of its kind individualized neoantigen treatment. Those dialogues are detailed. And I think broadly, we are very aligned, both ourselves and Merck with those regulators.

It is with CIBA FDA, but obviously, other offices are involved because it is an oncology therapy of high import, it gets a lot of attention. And I would just say, generally, we're working closely with regulators to make sure that we're doing everything they want so that they can conduct rapid reviews of the file.

Merck is our partner in this. Merck is the sponsor for the Phase 3 study. So they -- we and they participate in those discussions and back and forth, and we each have different responsibilities in our 50-50 joint venture partnership. But the BLA submission, if it goes forward, will be from Merck.

Operator

Thank you. Alec Stranahan, Bank of America.

Unidentified Participant

Hey guys, This is [Matthew] on for Alec. Maybe for RCC, can you walk us through what makes you confident that Phase 2 could be registrational? And what hazard ratio or benefit you think would be compelling? And then if you do need to run a Phase 3, curious whether you think KEYTRUDA be the appropriate comparator arm or whether KEYTRUDA [elutipan] combo would be preferred pending the LightSpark22 data.

Stephen Hoge - *Moderna Inc - President*

Yeah. That's a great question. One of the exciting things in oncology is it's a fast-moving space. And then individual histology is sometimes the standard of care will evolve and you're highlighting (inaudible) for RCC. Look, first, I'd say the Phase 2 study is blinded, it's powered.

And if we see a really significant or profound benefit. We haven't guided on what that hazard ratio will be, but let's assume it's something that would look really dramatic and highly statistically significant. Then it is structured so that it could be a registrational study.

But it wasn't initially intended empowered as that. It's not a Phase 3 study because our primary goal here was we wanted to confirm the hypothesis that INT works well across a range of tumors and in particular, places that we thought there was an opportunity to improve apron pembro as a standard of care.

And since we started and enrolled that study, there's obviously been the good news of the (inaudible) result. Again, that's with our partner, Merck. And so if we see equally great response here for INT, we'll have a conversation with Merck about what we do with INT. It may mean going forward, it may mean adding it to those because there's always a desire to improve outcomes in cancer.

It will entirely depend upon what the data actually says. And so at this point, we're just excited to look forward to it. But once we have it, the thing that I think we will be most focused on is, does this confirm the opportunity for INT to work across a range of different cancers and other histologies?

Operator

Thank you one moment for our next question.

Cory Kasimov, Evercore.

Unidentified Participant

Hi, this is [Eddy] on for Cory. We had a question on the adjuvant melanoma as well, could you share how do you anticipate use across the broader PD-1, PD-L1 class or primarily only with pembrolizumab? Separately as subcu pembro and other options become more prevalent, do you see any impact on regimen selection, logistics or ultimately uptake for --

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Stephen Hoge - *Moderna Inc - President*

Thank you for both questions. So first, I think we will be pursuing a label. Obviously, it's on top of a standard of care in the trial, which is pembro, but we believe that, that label could broadly apply to other PD-1, PD-L1s that are approved in the same indication for adjuvant melanoma.

Obviously, that will depend upon discussions with regulators, but I think that would follow the precedent of other approaches. And it's in our mutual interest with Merck. We want to see INT be used for as many patients as possible. regardless of the choice of the PD-1 or PD-L1 backbone.

The -- as it relates to subcu, I think that's really within the PD-1 class question. And so how do those antibodies get subbed out for each other going forward. It really wouldn't really, in our mind, to INT, which would be a category of one and the benefit that INT provides, we believe, would apply equally well, although we'll have to see what regulators want to see this.

But I think the community would agree that would likely apply equally well whether you're doing a subcutaneous or IV use of PD-1 antibody. But that's really a question about what they're doing in terms of class share there because INT will be in a category unto itself.

Operator

Thank you.

Ladies and gentlemen, this does conclude the Q&A portion of today's presentation. I'd like to turn the call back to Stephane for any further remarks

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

Well, thank you very much, everybody, for joining. We look forward to speaking to many of you in the coming hours, days and weeks. Have a great day.

Thank you.

Operator

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