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EDITED TRANSCRIPT

MRNA.OQ - Moderna Inc at JPMorgan Healthcare Conference

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OVERVIEW:

Company Summary

LSEG DATA & ANALYTICS

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PRESENTATION

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Great. Welcome, everyone. My name is Jessica Fye, large-cap biotech analyst at JPMorgan. We're continuing the 44th Annual JPMorgan Healthcare Conference today with Moderna.

First, you're going to hear a presentation about the company. And then, we're going to go into some Q&A. (Event Instructions)

With that, let me pass it over to Moderna's CEO, Stéphane Bancel.

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

Thank you, Jessica. Good afternoon and welcome to Moderna's presentation at this year's JPMorgan conference.

Let me start by reminding you that we're going to be making forward-looking statements. You can find those on our website or on the SEC website.

What we're working with the team to do in the next few years is, basically, to build a respiratory vaccine franchise to generate cash to be able to invest in our oncology and our rare disease assets.

If you look at it, we are quite underway. We have now three products approved by the FDA and around the world. We have two products that we've submitted to regulatory approval, flu and flu plus COVID. And then, norovirus is in Phase 3. In oncology -- and we're going to come back to it in a minute -- we have a very exciting pipeline full of catalysts in 2026. So we are very excited to see what we can do to help patients.

But let me start by 2025. In 2025, our sales guidance was $1.6 billion to $2 billion. We're very pleased to report this morning that we think -- this is pre-audited numbers -- that we should land around $1.9 billion of sales for the year, which is $100 million better than the midpoint of the range.

We got three products approved in the year. We filed products for flu and flu plus COVID for approval. We have quite a number of catalysts in the pipeline. So the R&D team was very busy to build the future of the company and to diversify away from COVID to grow the company.

As you know, we have been marching towards a multiyear process to resizing the company because, of course, the very high demand we had during COVID is not necessary in the endemic setting. And so we had to do a lot of restructuring.

I'm very, very proud of the work that the team has done over the last few years. In 2024, we had around $6.3 billion of cash cost for the company. At JPMorgan last year, we set the ambitious goal to deliver $5.5 billion of cash cost for a year. Quite a number of people were not so sure we could achieve it.

Well, the great news is for an amazing work by the team across the entire company, across the entire P&L and the balance sheet and the working capital, we, in August, on the Q2 call, said that we should land around $5.1 billion cash cost. At the Q3 call, we said $4.6 billion.

This morning, we announced -- and, again, those numbers are unaudited; we are going to go through the audit process. We think we should finish the year at $4.3 billion to $4.5 billion of cash cost.

So if you look at it just compared to last year, the team has worked across the board to take almost $2 billion of cost for the company. That is a massive achievement. I'm extremely grateful for all the team and for our CFO, Jamie, to driving the charge across the company.

Really, it has been everything, working with suppliers. We're making business processes, renegotiating prices, taking down manufacturing, working on the working capital and everything. We left no stone unturned. We're still turning stones, as we speak.

So with the sales in a good place and costs in a much better place, we are very pleased where we're finishing the year in cash. Last year, at our Q4 earnings call in February, we said we think we should end 2025 with $6 billion of cash. In November, we raised that to a range of $6.5 billion to $7 billion. And if you look at the cash we had at the end of the year before the drawdown from the credit facility, we achieved $7.6 billion.

This is all within our control on a like-for-like basis. So it's a tremendous achievement by the team. You add on to that, the line of credit, the drawdown we did from Ares in November, that takes us to an actual cash balance, cash and cash equivalent at the end of '25 of $8.1 billion.

And because we still have $900 million we can draw down from the facility, we have actually a credit facility giving us liquidity of $9 billion. So we think we are really in a great place to be able to navigate the growth over the next few years.

So if I now run to 2026, '27 and '28, we are very focused on driving profitability back to the company by 2028. And for that, we see two big drivers of growth in '26, '27 and '28 in terms of sales. One is geographic diversification, which I think is really important. And the other one is, of course, new product launches.

So if you look at '26, we think we can grow the sales and we can grow the sales potentially up to 10%. So the first vector of growth is going to be the partnerships we have in the UK, in Canada, and Australia, where we agreed with the government a few years ago to build dedicated factories in their countries in exchange for basically a multiyear partnership in terms of volume commitment.

And those are really long-term partnerships. They have also R&D investment across the country, including in the academic labs of those countries. There's also a national defense and the pandemic readiness clause in those contracts, meaning we can any day flip those factories into pandemic factories. If God forbid, there was an H5 outbreak tomorrow, we could in any of those countries at the government's decision, flip any percent of our capacity towards pandemic readiness onshore.

The other thing, of course, is new product growth. So last year, we're very pleased to get mNEXSPIKE a vaccine with a higher efficacy for COVID versus Spikevax approved by the FDA. We're starting to get approval around the world, and that will drive organic growth. And in the US, because we didn't have a full year of launch with a full year of launch because we have higher efficacy, we're seeing a very good response from customers. We saw 24% market share in the retail segment. And if you look at the elderly segment, we actually achieved a 32% market share in the first year.

We believe that for a full year of contracting, we should be able to achieve potentially better than that. And with the launches in the countries listed on the slide, this should really drive growth. So if you think about the geographic growth we're going to get from a basis standpoint in UK, Canada, Australia, and the mNEXSPIKE, continued growth in the US and new growth outside the US, that will help Moderna grow for the first time in a few years in 2026.

Then if you look into 2027, which we're already preparing right now, we are quite excited about the opportunities ahead of us. And the first one is in Europe. As some of you know or might remember, we have been excluded from the European market for now several years because of a partnership between Pfizer and the EU, which expires at the end of '26. So we're going to get access again to the COVID market, which is a very big market in Europe. In Europe, you have 90 million people compared to 60 million people in the US above 65 years of age.

And the price differential on vaccine is not very, very high. So the volume and the number of people you can treat is actually really important. The other piece that could be very, very helpful to us in terms of sales growth in '27 is the flu plus COVID combo.

If we're able to get an approval of flu plus COVID combo in Europe in 2026 that will allow us to get NittA recommendations, so CDC equivalent recommendations and pricing negotiation to be able for the winter of '27, '28 to be able to be in the market. And most probably given where other products are right now, we will be the only product in the market with flu plus COVID combo. So we think that's really important for '27.

The other piece we are doing to continue to drive geographic expansion is to do more partnership with governments like we've done in the UK around the world. We are very pleased to announce a partnership with Brazil that is ongoing. And we are discussing several other partnerships to be able to extend those multiyear agreements.

And of course, in '27, with a flu already being filed, we should have an approval starting in flu in '26, the balance in '27, allowing us for sales impact in '27. And in '28, we should have flu plus COVID, including in the US, Norovirus if the Phase 3 is positive.

So as you can see, you have this accumulation of new product up to six products in the vaccine portfolio of Moderna by 2028, driving growth not only in the US, but very importantly, outside the US. So that's how we see the growth over the next few years.

So with that growth, we're going to see an expansion in gross margin because we have bigger volume, and we're going to continue to work on yield and improvement in productivity and manufacturing. R&D costs, as we said at R&D Day in November, are going to come down because we're not going to commit to new Phase 3. So we basically have the sunsetting of the existing Phase 3.

Even a product like mNEXSPIKE, even though it's launched, we still have Phase 3 cost commitment for safety follow-up. But as those things sunset, we're going to have a reduction of R&D for vaccines. The SG&A investment should be pretty flat because we don't need to add sales force capacity to sell seasonal vaccine in the US to the retail or to the hospital.

And so there's going to be a pretty interesting story in terms of EBIT and cash generation to invest in oncology and in rare disease. So in oncology, we are very excited about 2026. If you look at Intismeran that is combined with KEYTRUDA, we have now 10 clinical studies ongoing. We have three Phase 3 study. We have five Phase 2 across multiple tumor type, and you have two Phase 1.

And then there are the next wave of oncology products coming, and those are fully owned by Moderna. mRNA-4359, we spoke a lot about this year. We saw interesting signals in the Phase 1/2 early in the year. And what we did with the team, we very quickly reprioritized the portfolio to not increase R&D costs because we want to be very disciplined about cost. And we basically funded the Phase 2 in lung and melanoma for 4359.

459 is used in metastatic setting. And what we have seen is patients that were refractory, meaning they did not respond to checkpoints like KEYTRUDA and Durva and the others. And then you give them KEYTRUDA plus 4359, and we saw a pretty high response rate. Of course, it was a Phase 2, so the end is small, which is why we are chasing this signal. The patient stories are quite moving when you hear those patients that went through one checkpoint, Stage 4 cancer, do not respond, go to a second checkpoint, do not respond, get our drugs.

There's actually a patient who did a testimony in the Guardian, I think, last week. explaining that now she's tumor-free she Stage 4 cancer patient. So again, it's early studies. We're doing the right thing, which is chasing the signal. This is an asset we own, but because it's Stage 4 cancer, this could go very fast and there's potential read-out in 2026.

And then there's some earlier drugs that we are very excited about like mRNA-2808. It's a T-cell engager making free antibody at the same time in multiple myeloma. So we think this should improve care to patients. And again, we are going into the clinic, doing dose escalation. And if we get signal in patients, we'll expand this very quickly to see if we can improve patient care.

Then you have a couple of more programs that are early, but they're going to progress pretty quickly. And then on rare disease, PA should read its Phase 3 in 2026. The FDA endpoint is a 12-month endpoint. We announced at our November earnings call that we were fully enrolled.

So you can do the math yourself; by the end of the year in 2026, we should have a Phase 3 data. And MMA is ready to move into pivotal study. Again, we want to be disciplined about investments. So we'll not move this until we have signal on PA, but it's ready to go into Phase 3 study.

And so if you think about it, with Intismeran potentially reading its Phase 3 in '26, that could be a '27 launch. And then with PA reading its Phase 3 and with 4359 having a potential Phase 2 in a setup metastatic disease where patients do not respond to checkpoint. That is really game-changing for patients. So that also could be an accelerated approval in '28.

And then there's other products that a lot of people don't pay too much attention to right now, but are quite important. If PA works, the read across to MMA is pretty strong. It's a same lipid. It's also a rare disease in the liver exactly like PA is. And we've had some very interesting data out of the Phase 1/2. We have the other oncology asset I started to talk about.

And then in vaccine, we still have a few interesting assets. We have currently a Phase 2 study, multiple sclerosis treatment that is an EBV product. As you know, there's been a lot of progress in the field on the hypothesis that MS is mostly induced by EBV activation.

And so what if you could use a technology to control the viral load of EBV-positive patients like you do with HIV, to control the viral load so that you don't have flares of MS. That's what we are trying right now in the clinic in MS patients. We're also working in the clinic on a Phase 2 study for an EBV vaccine that is prophylactic to be used in teenagers a bit like you have for HPV, a vaccine that could be used with teenagers to prevent mononucleosis.

And if positive and approved, you could potentially do a very large study with the government to look at scale. Could you prevent multiple sclerosis? It's a bit like what Merck did very successfully with HPV. This is a very interesting product because we think the unmet medical need is very large, not only for MS, but EBV has been shown to also drive some cancer, which is not surprising, having a virus in your body all your life as you age and the immune system becomes weaker might not be a great thing for our health.

We have a Lyme vaccine in the clinic, which is our first antibacterial vaccine before it was only antiviral and CMV ongoing in transplant. So quite a number of products that could also complement the sales in the coming years. And then we have a lot of products waiting to go into the clinic because the team is very active with the platform. And the more they learn about the platform and the mRNA technology, the more they have ideas in infectious disease, in cancer and also we are playing with autoimmune disease.

We've committed to continue to be very disciplined about cost. Our goal is very clear. We want to drive breakeven -- cash breakeven in 2028. So we continue to work on cost to reduce the cost as we increase the top line with those product launches and those geographic expansion.

So to close, maybe if you look at 2026, we are quite excited about 2026. The last few years have been difficult, as you can imagine, resizing the company coming from the scale up that the team did an amazing job during COVID was difficult.

And of course, last year was difficult with all the changes in the vaccine field. But if you look at '26 commercially between the geographic expansion that is happening because those plants have been approved by their local regulators. So you're going to have a base effect in terms of full year impact of sales in Canada, UK and Australia. and mNEXSPIKE growth in the US, both market share for the full year and expansion on geographic, we are very excited to go back into sales growth.

Then the pipeline, there's going to be a lot of catalysts in 2026. mNEXSPIKE approvals, flu plus COVID combo in Europe and Canada for potential approval and flu in US and Canada and a few other countries, we provided a list last Monday.

And then, of course, Intismeran. If you look at the list, there's a world when there is a lot with that on Intismeran. What we should get very soon is the five-year data of a Phase 2 in melanoma. That should come very soon. That will be really important because five years is a very important point in cancer treatment. We've shown the two years, we showed the three years, the three years were better than the two years. So we're really eager to see the five years and to share it with you.

Then, of course, the Phase 3 in melanoma, but also because RCC, renal cell carcinoma is fully enrolled and has been for a while. We could have data in Phase 2 in RCC. Also, we have several Phase 1 ongoing in pancreas cancer and also gastric cancer. So those things could read out, and we will share, of course, the data. So I think we could move from a world where a lot of people are quite hesitant about INT or Intismeran to a world where you have a different tumor from melanoma and you have a Phase 3 and you have duration. So it's going to be a very exciting year.

And we are really working hard with our colleagues at Merck to be ready to potentially file very quickly. The factory is ready in Marlborough, Massachusetts. So the product is fully made in America. And we should be able to move pretty quickly as the teams are preparing for BLA filings of the CMC package. We could have because it's in metastatic setting, some read-outs in the Phase 2 of 4359.

Norovirus should read this year, as it should, knocking on wood, is last year, we got unlucky with the epidemiology, the strain of the virus. This year, so far in the season is tracking positively. So again, I want to be cautious because we don't control the strain of virus circulating. But we think we have a good chance to read out this year. And of course, the PA is going to have a mechanical read-out this year. We're going to continue to work on cost and continue to drive productivity for throughout the whole company.

So sales growth for '26, expansion of potentially up to two new product approvals. So we could go from three products approved today to potentially five by the same time next year and a lot of clinical read-out in oncology, in infectious disease and also in rare disease. So we're quite excited about '26.

QUESTIONS AND ANSWERS

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Great. (Event Instructions)

But I will start. So for Intismeran, with the potential for that interim read-out from the Phase 3 trial in adjuvant melanoma coming up, what effect size do you need to see to claim success at the first interim?

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

Sure. It's nice to start by the question on Intismeran. You get the question on COVID right the way. So Intismeran, if you look at what we've done in the Phase 2, so just to reground everybody, the Phase 2 was a randomized study with a 2:1 ratio between Intismeran plus KEYTRUDA to Intismeran. And because it was randomized and it was 157 people -- sorry, patients, it's quite a good-sized study.

And if you remember what we saw, we saw -- the three-year data being better than the two-year data, which is always encouraging in oncology compared to KEYTRUDA monotherapy. We saw a DFS of around 49%. So one in two people benefited from a DFS standpoint compared to KEYTRUDA mono. And in DMFS, distance metastasis-free survival, which oncologists think is a very interesting metric for long-term survival because, of course, people die of metastasis, not the primary tumors, was actually 62% -- and the p-values were very strong. And so we're going to get the five-year data soon.

So I think that gives us a better sense of how well does the signal hold. And so as you know, when you go to Phase 3, it's really hard to know if you get the same type of numbers or not. But because of the mechanism of action of a drug, which is really -- and we showed that at ASCO in 2018 is really to reprogram the T cell of the patient. We think we should have nice duration and nice effect size.

So we have not disclosed with Merck where the goalpost is, but I think if we see a material improvement versus KEYTRUDA alone, if you just look at the number of lives impacted, we think there's a product there. So --

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Jessica Fye - *JPMorgan Chase & Co - Analyst*

What about a scenario where we don't hear about an interim read-out from the Phase 3 this year? What would the most likely reason be?

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

Sure. So as I mentioned, this is an event-based study like most Phase 3s in cancer. So if we don't have data this year, given that now we have reconfirmed '26 several times, if you look at the last few quarters, our statistician look regularly at the data set, what we know number of events and so on.

This might be actually a good news because it means that we don't have events, meaning people don't have their cancer coming back, which might be very good news for the drug and for patients. So I will not panic if we don't get the data in '26.

We think it should come in '26. But again, it's event-based. And I think every month, it's delayed, it might be a good sign.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Okay. So what about the read across to other settings, right? So to what extent if we do get positive Phase 3 data in adjuvant melanoma, does that read across to other settings? So how would it?

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

So with oncology, one always has to be cautious. We will have to do the clinical studies, which is why Merck and ourselves are invested in those nine additional studies to melanoma. But if you go back to what we showed at ASCO over the last few years, including pre-COVID, we had signal.

So again, it was a small sample in the Phase 1/2, which was an all-comer study in lung, we had signaled in head and neck -- and so Merck and us believe that because of the mechanism of action and because KEYTRUDA has worked in so many tumors that we should have an incremental patient benefit compared to KEYTRUDA alone. I think, again, given all the things we collectively don't know about cancer and about the drug yet, it will be arrogant or unscientific to actually make any claim about the effect size we could see in other tumor, which is also why we are very eager to see what signal do we get or not in those Phase 1.

They're going to be, of course, small numbers. But if in gastric and/or in pancreas, you see signal, that's interesting and then the Phase 2 like RCC and others and bladder. So we should be -- because a lot of data should come this year, which should potentially be sitting here this year if we invite us with actually quite a number of read-outs where we'll be much better informed by the true potential of Intismeran.

Because, of course, if it's a drug only in adjuvant setting, melanoma is going to be great, but it's going to be in the many billions of dollars. But if you have multi-tumor responding, if you have metastatic, you might have seen this two study in metastatic setting in lung and in melanoma, then you can start to see, okay, this is really like a very impactful drug that's going to save a lot of lives, just if you look at the effect size, and that's going to be a big commercial product.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Related to that, can you just take us through -- so like the five-year follow-up on the Phase 2, we're certainly getting that this year. And then what's the cadence of the updates after that?

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

So you're going to get it this year because the two-year and the three-year data came in December. So because it's a five-year study, we have to do a lot of cleanup and scans and so on to make sure everything is right before we lock down everything. It's the end of the study. So because he was December of the two and the three year, we're talking weeks or months, I'm not talking quarters.

Then for the other read-outs, it's really hard to predict because those are all event-driven. All the studies are event-driven. So could I see a world where we see melanoma sometime this year and before there's maybe another study that has read out? Yes. Could there be studies on both sides of the Phase 3 melanoma? Yes.

It's really hard to predict. We just share the data as we have them. We always do that. When good data like flu, I think shared it 48 hours after we got the data or bad like CMV, we shared also, I think, two days after we got the data. We'll get the data out.

We want the scientific community to know about the data. We want to be transparent with investors. So as soon as we know, you know probably quickly right after.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Okay. So you mentioned a couple of metastatic studies. What is your latest thinking on the potential for this approach in metastatic disease --

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

Sure. So I think it comes from what we are learning with our colleagues at Merck, not only about Intismeran, but also the other products of Moderna and also the field. If you look at it, what we have seen with 4359 in metastatic setting is really interesting that mRNA technology can have an impact in metastatic setting. If you look at what we have learned about T cells and all the biomarker we've looked at across all the studies listed, we've learned a lot. We keep learning a lot.

We keep digging at data. We keep looking at the new antigen and so on. And so we believe it's a quite interesting possibility that INT because of disability to really reprogram T cell, which again, for those that have not seen the data, I go back to ASCO 2018 or AS Lavina, she'll get you the data. Once you've seen that data that you can see in patients that if you take their blood before starting Intismeran and you look at the antigen coded in the Intismeran drug, the T cell response. And then you look at four dose after and you take the blood of those same patients and you see T cells popping up, that's quite profound.

And so with a lot of things we have learned, Merck and us because we have to go through GSE process and to mutually agree to do the investment because we have 50-50 cost-wise on those studies. And there's already always more ideas by our oncology colleagues than we have resources that we didn't go lightly into metastatic setting. We think there's a chance for having a signal there. But again, with oncology, you have to be cautious.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Beyond Intismeran, what other assets are you most excited about in the oncology pipeline? And how are you prioritizing them? And just what are the next read-outs we should be watching for that aren't Intismeran?

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

Sure. So one I mentioned briefly is mRNA-4359. We expected signal based on the mechanism of action, but we didn't expect what we saw. And the patient stories we reviewed with the team were very profound. You have people 70-year-old, Stage 4 skin cancer, you have metastasis everywhere, get on the checkpoint, go through the whole cycle, no response.

Get another checkpoint, go a full cycle, no response, get on to sometimes a third checkpoint, no response and then get on to 4359 plus KEYTRUDA. When if you think about it, the disease is much more progressed. And the immune system, which is a key component of how our technology works, is also weaker, and we've seen responses. So again, it's Phase 1/2, it was early data. So the end is small, but it was in melanoma and in lung, which is always a little pin for the Intismeran question across tumor types.

And so what we decided with the team is like we need -- look, we need to chase that signal. And so because we're so disciplined on cost, we just look at the whole portfolio, we delayed other things to be able to fund, which was not in our initial 2025 plan to fund the Phase 2 in lung and in melanoma. And because those are metastatic patients and the control arm, of course, are not getting 459, you have a case where you could have data in '26. And so that's something also that could be quite a surprise because then you could go very quickly to regulators. There is no manufacturing critical path because this is done in Norwood.

And because it's metastatic setting for patients who do not respond to checkpoints, what do you have left when you have a patient and you've gone for two or three or four checkpoints and you don't respond. So that's quite exciting. The other one I'm quite excited about is 2808 in multiple myeloma. As you know, the standard of care is you go antibody after antibody when the cancer escape. What if you could have one product with three antibodies in a single dose to try to really stop the cancer from evading.

It's in the clinic right now. in patients, obviously. And so we get data of this. So this is one that I see as a low biology risk because those are targets that have been used in the field. Some of them are products approved.

But it's a good use of the mRNA technology where you can combine all those things, you can go quickly in the clinic. There's incredible manufacturing leverage. We can make that between two COVID batches. And so that's another one that I'm quite excited about in oncology. But there is more coming.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Any pipeline questions from the audience?

Maybe shifting to the financial outlook. Can you talk about what supports your ambition to deliver up to 10% revenue growth in 2026?

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

Sure. So I think we need to look at the US and outside the US, in the US, if you look at this year, there's been a decrease of the COVID volume. A lot of it is due to the start of the season. As you know, the start of the season with the products approved, but with a new AC panel recommendation.

In a lot of states, pharmacies could not deliver the vaccine if you walked in a pharmacy and ask for a COVID vaccine. So it took several weeks. Some states move very quickly. But even in a state like Massachusetts, where we live, you could not walk into a pharmacy, I want a COVID shot, I couldn't give it to you if you don't have a script. Of course, you had a script because the product was approved by the FDA with an SBLA, you could get the product.

But if you were without a script, you wouldn't get the product. So some states move very quickly to allow pharmacies for local public health decrease for the state to allow this to happen. Some states took like a month. And so that was, of course, not helpful. What is interesting is if you look at the last month or so, the decrease compared to last year is quite modest.

Another thing to appreciate is that the guideline for the spring booster is still for COVID shot for the spring for people at high risk, the elderly and people at high risk cancer people, patients and so on. And so even if the US were to go down a little bit in volume, like we've seen in the last month, -- if you think about mNEXSPIKE, which because of high efficacy has a premium price and the share we are potentially going to be able to gain into 2026 because with a product approved, it's a much less risky proposition for the retailers.

That should help to potentially even have a flat sales in dollars if we had a small decrease of the volume of COVID. But with what's happening in flu and with COVID right now in the country, people might be more motivated to get a flu shot because I think too many people still do not understand that when you get a viral infection, if you have it for several days and you start coughing and you damage your mucus, you're going to start to have bacteria going down from upper track to lower track and that's how you get pneumonia.

And if you get pneumonia for too long, that's how you get sepsis. So if you think about the cascade that we see a lot in people at high risk, that's the cascade, which is why if you're at high risk, you absolutely need to get a vaccine for all those viruses because any one of those can be done. And if you're unlucky, you can come from a through infection and be recovering from it, still not be in great shape. And then you get COVID or vice versa. And that's the second one that really put you down and you get pneumonia and then you're done in downward spiral. And so that's for the US.

Outside the US, as we said, there's two things, the incremental from zero of mNEXSPIKE sales in many countries. And two is the deals we have in Canada, UK, Australia. In '25, you only had part of the years where you had revenues because the factories were not approved until late. But next year, you're going to have a full year effect.

So if you just from a basis standpoint, you just want to get mechanical growth from there.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

So underlying the up to 10%, which direction is the US going if we think US volume is maybe drifting, but mNEXSPIKE.

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

Look, it's a bit too early to tell, which is why we're not guiding precisely. The contracting season is ahead of us. We're going to try, of course, to do the best we can to get as much share as we can. I'm sure competitors will be fighting back. The uptake we saw in the first half season is pretty good.

And so we're quite optimistic. But until we get the contracts, we want to have more precision. So I just want to stay cautious because there's a lot of contracts to happen in the next six months. But as I said, even if the US were to be flat in dollar, we'll grow -- the company will grow outside the US

mNEXSPIKE and those three countries where we're going to have a very material FX size.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Walking through the flu and then flu COVID timelines. Just first, what season do you expect the monotherapy flu vaccine to launch? And how do you plan to drive adoption of that product?

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

Sure. So for flu mono, mRNA-1010, we have filed in all the key geographies. There's more coming. The regulatory team like in most companies prioritize and just get going. So there's more coming.

But because of the time lines, if some countries approve the product in 2026, which we expect, you should see minimum, if no sales. because by the time you get the product approved, contracting is behind you. The retailers want the product for the season to guarantee their EBIT margin and serving the customers. So there will be some potential tactical sales right and left. But the true impact of mRNA-1010, if it's approved by regulators is really in '27, which is why I talked about it in my '27 growth.

Same with COVID plus flu, if it's approved in Europe, given the time line should lead to a '26 approval based on when we filed it. It will have most probably no sales in 2026 because by the time you get it approved in Europe, you need to go country by country to get the CDC equivalent, the NTA recommendations. And then you need to negotiate pricing by country. Pricing is not at the European level, it by country.

But what we're really trying to aim there and the timing works really well because remember, in '26, anyway, there's a COVID Pfizer contract, block on COVID and government, given their budget situation, do not want to spent buying a COVID mono and then buying a COVID flu combo.

But what is key for us is to play the timelines, we should be able to do all that to get into '27, early '27 to be able to be in countries where you have tenders like Spain and Italy, be able to participate in all the tenders and in countries where it's negotiation with government to be able to do that. So we really expect flu COVID sales if again, the product is approved to really have a big impact in '27.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

And what about flu COVID in the US? What's the status of that?

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

Yes. So as you know, Jessica, it's more for the audience. We had filed COVID flu in the US. When we got the Phase 3 flu data, the FDA so a bit earlier in the press release, they asked us to basically withdraw the file of a combo and refile after we filed flu. So we just filed flu just before Christmas. We just announced it last week. And so we are in active discussion with the FDA of what timing will be appropriate to refile the flu post-COVID combo.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Okay. So that's launch season for the US.

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

So that's why we did it for '28 to be conservative. Okay. If you look at the slide I presented, it's not for '27, it's for '28. '27 is really flu US and Europe reopening and flu plus COVID in Europe.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Okay. You also talked about once Europe is back on the table, having more volume and that helping you drive better gross margins. How much does gross margin improvement from here hang on top-line growth?

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

So it's interesting. We have not given the split, but if you think about gross margin in the next three to four years, let's say, you're going to have a few things. You're going to have pure volume, all those product launches in vaccines. Then when we have non-vaccine product to launch like PA, mRNA-4359 in cancer, mRNA-2808, those products will be made off-season of respiratory vaccine.

Because today, if you think about it, we are really penalized in terms of gross margin because in Q1, the factory is not very busy because we supply the Southern Hemisphere, it's not big volumes. And so you could make PA product or any of those other products that are not individualized in your off-season timeline, absorbing your fixed cost. So that will be helping.

The other piece is that the team is continuing to work on productivity internally in terms of yield, in terms of reducing deviation, be able to -- and then the third piece is productivity through AI. We're doing a lot of investment in AI across the company. We're still negotiating with suppliers better deals.

And the last piece, which we announced at R&D Day, is we are bringing for the US market prefilled syringe manufacturing in Norwood. And so this also should improve margin because today, we pay a third party and we pay the margin and we pay the taxes. When we bring this, we're actually going to amortize the fixed cost of Norwood, including the assets, the building which we own and the personnel. So I think that's going to -- so you see there's four, five levers of gross margin improvement.

But again, in the next one, two, three, four years. It's not a magic one that next year, it's going to be a continuous improvement. I really think year on year, it's going to be better and better.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Okay. Great. That is it for our time. So we'll stop there.

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

Thank you.

Jessica Fye - *JPMorgan Chase & Co - Analyst*

Thank you.