Moderna

Moderna presentation delivered at the 43rd Annual J.P. Morgan Healthcare Conference on Monday, January 13, 2025 at 3:45 PM

Jess Fye: Welcome, everyone. My name's Jess Fye. I'm a biotech analyst at J.P. Morgan.

The next company coming up is Moderna. The company is going to give a presentation. Then we're going to go into Q&A. If you have a question, someone could bring you a mic or you can send them up to me at the iPad. That might be easier.

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

Stephane Bancel: Thank you, Jess. Good afternoon. Let me start by reminding you that we'll be making forward-looking statements. You can find those statements on the SEC or Moderna's website.

Today, I'm going to start by talking briefly about the Moderna platform. Then I will recap 2024. Then we'll go into the future, our objectives, our outlook, and important milestones for the year.

We started Moderna because we were very intrigued about the possibility to have mRNA as an information molecule to make protein in vivo in the human body.

We thought if this was possible, we would be able to make a lot of medicines that cannot be done using recombinant technology. We thought because we use always the same chemicals to make the mRNA that we will have a much higher R&D productivity.

We thought if we could industrialize this platform for process development and manufacturing, we could go much faster than recombinants. We've thought that because we make our products in the same reactors, we'll have greater capital efficiency.

From the get go, we set up our vision to build a platform. The tools, systems, processes to be able to invest in mRNA science, invest in delivery systems, invest in manufacturing to be able to get many, many medicine out for patient and creating value for shareholders on the way.

One other thing that has panned out to be true from those beliefs we had in the early days is that, if you look at the last 10-plus years of a company existence the difference of probability of technical success of Moderna in red versus the rest of industry in blue.

You can see that in phase I, we're consistently much higher than the industry. Phase II, consistently, we're higher than the industry. Phase III, a little bit higher. If you compound those numbers and you look at the probability of an asset to go from phase I to approval, we're actually six times higher than the industry average, which we think is a very important benefit from a value standpoint of this platform.

If you recap quickly, 2024, we said, in terms of sales, we will achieve 3 to 3.5 billion of sales. In term of actuals, we announced this morning, we should be on the low end of these, 3 to 3.1 billion once the team finishes auditing the number.

Very importantly, in cash, we said we should finish the year with $9 billion of cash. I'm very thankful and very pleased to announce that, thanks to the hard work of the team in terms of managing expenses, managing capex, and also managing working capital, we're able to finish the year at $9.5 billion of cash.

The other thing that we delivered during the year was, of course, the approval of RSV, our second product in the company history. We had a very busy year in terms of clinical readouts for Phase 3. We had four Phase 3 positive clinical readouts. The first three on that list have actually been filed to the FDA.

I'm also very thankful for the team that have accomplished, in only three months, three BLA filing. For a company of size and with our track record and history, this is really an amazing accomplishment by our teams.

Then, if you look across the pipeline, we still have multiple positive data. We have positive data in Phase 1, 2 in norovirus, in EBV, in VZV. I'm very pleased to report that norovirus is now enrolling in the Phase 3 study. We could have a readout in '25 or '26 based on cases.

We've showed some very exciting data in terms of duration of our INT oncology product combined with Keytruda. We have now a very exciting three-year data that are actually better than the two-year data. We have also showed some early intriguing data in Phase 1/2 for checkpoint vaccine, a PD-L1 and IDO1 vaccine that has been presented at ESMO earlier in the fall.

Also, our rare disease program, PA and MMA, that are both metabolic disease. Now, PA is actually, we've announced this morning, currently recruiting patient in its pivotal registration study, which is exciting for patients because today there is no drug available for patients with PA disease. It's a metabolic disease. MMA should be dosing in its pivotal study soon in 2025.

If we look forward, what we shared at R&D Day in 2024 is that our three priorities are pretty clear. The top priority is to drive revenues based on the approved products, COVID and RSV.

We have been investing heavily over the last few years in a very broad pipeline to diversify from COVID and to drive sales growth again. We're really focused on the 10 products that we have the opportunity to launch over the next four years.

Also, we are very focused on driving cost efficiency across the entire company, and I will come back on those three topics.

First, in terms of sales, what we saw in 2024 is a stabilization of a COVID market. If you look at the COVID market, and we only have a data in retail right now, but the US retail market was actually down seven percent, which is much less than in the past.

What is very important for us is that what we think is the recurring business over 65 plus, people at the highest risk of COVID, as you can see, was only down two percent. There's good hope that we're getting to the bottom of the COVID market in the US. The 64 and under, as you can see, was down 12 percent.

Entering 2025, we have two products to be able to provide to our customers as we go into negotiation for the fall of '25. We are getting RSV approved in more and more markets outside the US, giving us the opportunities to increase sales in those geographies.

Today, we communicated that guidance for 2025 is 1.5 to 2.5 billion dollar, compared to the 3 billion dollar to 3.1 that we achieved.

I think it's important to start by normalizing the year. We communicated in 2024 that we had around $200 million in the US. That was due to returns that were reserved in 2023 because it was the first year that we're a commercial company, and it was really difficult to estimate how much return we're going to get.

Then internationally, because of change in demand in vaccination in all key countries, there's around $400 million for advanced post-transplant that is also not going to be recurring next year. If you take those out, you look that the high end of the guidance is a flat year.

As you all know, there are a lot of uncertainties right now, and we wanted to reflect that with a wider guidance. There are uncertainties on vaccination rates. There's uncertainty on competitive environment and market share. There are uncertainties in terms of the timing of our readiness of our factories in the UK and Australia.

Depending on when those get approved by local regulators, we will have sales of different levels because they will still have to order products, but it will be through tender process. This will see as the year evolve.

For RSV, of course, ACIP recommendations are going to be really important to see what happens to the RSV market. There are some upside as well in term of vaccination rates. There's some upside in term of market share. One upside or so is some of new product sales. As I just said, we filed three product to the FDA so we could have up to three approvals this year.

Depending on when they happen, which we don't control, we've decided to not put any new product in that range of a guidance.

The priority number two is to drive sales growth by launching new products. I mentioned the three that we filed in 2024. There's still quite a number of readouts coming that are going to be exciting this year and next year for us to be able to launch those products.

Let's now talk a bit about cost. I think it's important to start by saying that for the company, managing our cash has always been really important. During COVID, we had to focus on speed for obvious reason of saving as many lives as we could, and we could never compromise on quality. Cost was not a high priority as we are to execute at a very high speed.

As we are going down to an end-of-peak market, the team has been now, for more than 18 months, very focused on reducing costs. As you look at cash costs, it's important to see the difference between gap cost and cash cost.

As you can see here on our '24 estimate, we have a gap cost of around 7,2 billion but cash cost at 6,5 billion because of stock-based compensation, depreciation, and amortization. It's quite a significant difference.

Let me tell you where we have been and where we're going. If you look at the data, we're around nine billion dollar of cash cost in 2023. This year, the estimate, we will report the number on the Q4 earning call, is that we should be around $6.5 billion based on how the first three quarters are trending of cash cost estimate for the year.

We announced this morning that because of this uncertainty on the top line that we are seeing in '25, we thought it was responsible and prudent to get ahead of this risk and to reduce our investments into the company just in case we end up at the low end of things.

We announced we are already taking a lot of actions across the company, across R&D, in terms of portfolio, in terms of productivity project, manufacturing, but also, SG&A to reduce our cash cost this year. Because some of those savings will come in the middle of a year, we estimate that there's an additional 500 million dollar of cost savings that will happen in '26 based on the work that is going to happen in '25 when you bake in a full year.

That is really important for us to be able to have a cost structure of around five billion dollar in '26. If you look at how we're managing the 9.5 billion of cash that we got at COVID proceed to invest in the business, to launch new product, to diversify the top line, to grow the top line, we basically reduced our net use of cash over the last few years and we intend to continue to reduce that as we launch new products and get to profitability in 2028.

One of the great opportunity we have is to really bring a lot of products to patients. If you look at the company's pipeline, which is the late stage pipeline. I remind you, we have 45 products in the clinic as we speak. As I said in our priorities, it's really focusing on those products that we could launch in the next couple of years.

We are trying to build a pretty unique respiratory franchise with COVID vaccine, RSV vaccine, flu plus COVID, flu vaccine as well to have a very, very robust franchise. We're also investing in latent virus vaccine against CMV and earlier in pipeline over viruses. Norovirus, which is now in phase 3, could be the first and only product to market for a while given the over vaccine status in other companies' pipeline.

We think there's a very large unmet medical need for norovirus. Also in term of bundling ability, with our China, with our retail China, we think it would be a very important asset to bring to them in terms of driving their growth over our net income. Of course, we're all extremely excited about cancer and we cannot wait to have a phase 3 data on a melanoma study combined with

KEYTRUDA.

As I said before, the phase 2 data was really exciting. We have enrolled in only 14 months around a thousand people around the world. It was a great endeavor by the team and we're looking forward now to get that data. From a manufacturing standpoint, because those products are individualized, we've also invested and have a plant that will not be in a critical path of launch.

As soon as we get the data, hoping it's a confirmation of a phase 2, we'll be working really hard to prepare, of course, the BLA and to file this for approval. If you look across this portfolio, there's a time of more than 30 billion dollar that we can address. For some of them, like I mentioned, norovirus, CMV and others, with no product on the market.

Those products will also be a very nice commercial combination with a product that we already have in terms of medical and sales and marketing infrastructure. Also, the rare disease will be interesting product because we don't need to build new factories for those rare disease, again, because the platform will be done in the same factory. Once the IND cost is behind us, the cost of sales and marketing, as you know, will be not very high.

And so that's going to be also very interesting for patients, but also to create a return for shareholders. The key milestones that we are looking forward to, of course, is the potential free approvals for the product that we just filed in the fall. A very interesting year with the CMV phase 3 readout, we have been told by the DSMB that we need to keep going on the study to go to a final efficacy readout that should happen later this year.

We have a phase 3 for seasonal flu and for norovirus that could readout this year based on cases. If we don't have enough cases, they will readout next year. I mentioned the INT phase 3 and the PN MMA. They have agreed with FDA endpoints, metabolic decomposition event for PA. There's a biomarker endpoint agreed with FDA on MMA.

And so we think that now with PA recruiting patients in pivotal studies, MMA is going to be recruiting very soon. We should be getting data actually pretty quickly. If you look at the key takeaway of today is that we achieved three billion dollars of sales.

We get our second product approved, we're able to restructure the business, and file free BLA during the year. Our three priorities are already what is driving our roadmap and the entire team is very focused on this. There's going to be quite a lot of catalyst and milestone happening this year between the phase 3 readout and the potential approval. With this, Jess, I'll be happy to take

your questions.

Jess: Thanks for the presentation. I don't know how to ask this without asking it bluntly, but how conservative is your new 2025 top line guidance, and what changed so much relative to when you last gave us those numbers that it's changing by one billion dollars today?

Stephane: Sure. There's a lot of factors. As I mentioned during my remarks, if you look at the 2.5 billion dollars,it's basically the normalization of 3 to 3.1 billion dollars, numbers that we see for 2024. And then there's a lot of uncertainty, some that were not clear before the season, before we gave a numbers. RSV is a good example.

The RSV market is much lower than we thought. The competitive environment has been much tougher on COVID. And then some countries have changed guidelines of recommendation. There are countries where you used to have recommendation 65 plus that now have moved to 75 plus.

Not in the US, but outside the US. We have quite a number of parameters like these that have changed. There's, of course, uncertainty on what will happen to a vaccination rate. We also didn't want to include the new products because we have learned from the RSV launch last year that including the new product forecast itself in the first year is a very dangerous endeavor.

We learned from that mistake, and we didn't do it in the guidance for next year. This is some of the factors that we took into consideration to have a guidance that we can deliver on.

Jess: OK. When you talk about competitiveness in the COVID market, does that mean price or share?

Stephane: A bit of both. There's been another portion on price in 2024 in the US. Share has also reduced versus '23, we think, a lot because of price but also bundling. If you think about Moderna compared to a lot of our competitors, we were in 2024 during contracting season in Q1 or Q2 a one product company.

And so, a lot of our competitors in the different field where we are able with a retail channel to bundle products, to provide discounts for bundles that we are not able to provide. One other thing that we're excited, if you look at '25, but especially '26, '27, is you're going to have potentially a next gen COVID with a higher efficacy that, uh, should be able to help because there's been nobody else with such a product.

We talked about potentially flu plus COVID combo. The norovirus. If you look again at the next couple of years, we should be able to be quite an attractive partner to the retail channels, helping us them driving growth. If you think about it, this is how we drive revenue growth.

See, the VCI is not moving for the market. It's not helping them. It's not helping us. We think this is going to put Moderna in a quite different competitive position over the next couple of years.

Jess: OK. It also looks like you've been able to identify more expense to pull out of the cost structure sooner than expected. If I recall in the past, I think you would characterize at least 2025 and maybe even the next year to an extent having less flexibility in the cost structure. How are you able to do it, and were any products products paused or shelved to achieve that?

Stephane: It's a great question. It goes back to what we have been saying all along, which is we want to invest the proceeds of COVID during the pandemic to build shareholder value, to bring new products to patients for the mid and long term. We don't think keeping the cash in T bills is going to be the way to create shareholder value.

We know the platform works. If you think about it, for many, many years in the company history in the early days, we didn't know. We believe the platform should work, but we didn't know.

Now we have two products approved. We have four positive phase III. We know the platform works. We think the best thing we can do for shareholders is to invest their capital to drive new products and to drive value in such a way.

At the same time, we also say that we're going to be very careful and disciplined about our cash burn and our investments. As we realized for before those changes and the uncertainty, that we have that I just described, because there's a possibility that we will be below the 2.5 billion, we needed to get ahead of it, not behind it.

What we discussed with the team from before looking at the top line that I just described and the budget and we discussed with our board when we presented the budget to the board is to say, we have to get ahead of this just in case we are in this point of the guidance or in the low range of our guidance. We cannot pedal back after and we need to get ahead of this.

We looked across the entire P&L both in terms of R&D portfolio, IEEE prioritization. We're also looking at it in terms of productivity. Same thing in manufacturing. There's still a lot of things we can do in terms of manufacturing productivity. Same thing in G&S, we're looking at everything,

but also on the CapEx.

There are some projects that we wanted to do that we say, "Look. We're going to wait a bit before doing those projects." The plant in Canada, UK, and Australia, as we spoke about, are almost finished. We're just having the talent of that. The Norwood plant is finished.

As we said, the plant for the cancer, the INT product, the personalized, individualized product is mostly done. The CapEx also is coming down. The team is doing also a lot of work with suppliers in terms of pricing, renegotiation, in terms of working capital.

The team is doing also a lot of work with suppliers in terms of pricing renegotiation, in terms of working capital. The team is working on all the levers that we have because every dollar matters, and we want to have those dollars to invest in the business and of course, to be as efficient as we can.

Jess: The 2028 breakeven guidance, you had penciled in a six-billion dollar top-line for that year. Now, if we're talking about OpEx materially lower than that in the short term, should we think about the '28 required revenue being lower, or do you still kind of see the products stacking up to six-billion dollar of revenue in '28 even with the pullback on that?

Sté**phane:** It goes back to the fact that we want to be responsible and disciplined and careful. As I said, we've run this company for most of its history, being extremely focused on cash and runway. You have the same Chairman, you have the same CEO, you have the same President of the company. You have the same leadership that has gone through building this company.

We made one mistake, which is...We made a lot of mistakes, but we made one big mistake, which is we were too rational about the vaccination rate in the US and the way it was going to transition from pandemic to endemic. If you think about it, last year, in the US, in the 65 and above, you had 3x more people hospitalized of COVID than flu, 3x, not two percent, 3x.

Yet, the vaccination rate of COVID is significantly lower than flu. It doesn't make any logical scientific sense. We were most probably too logical, too scientific, and we were wrong. We learned from that, which is reflected in the guidance, and we are also reflecting that into our cost structure.

If I had this information two years ago that we should not be rational, that people at high risk, like 65 and above will get more vaccination because of the risk of high hospitalization, we'll have

reduced the investments earlier, but that's one of the mistakes we made. We were too rational. I think we're not the only one, but we were too rational it. We learn from it and we move forward. We need to learn from our mistakes.

Jess: You also updated us on the interim for the CMV Phase III trial. I think in the past, you had suggested that the final data could come mere months after the interim. Is that still the right way to think about when we could next year on that study?

Sté**phane:** That's correct. If you look at the number of cases required for the first analysis, which just happened to the second and final analysis, it's not a lot of cases in difference. As you know, those studies when they enroll, there's an acceleration in enrollment, so it's not surprising that you should be able to accelerate the number of case readouts.

We confirm that based on where we are now in the cases we are seeing, we should be able, pretty rapidly, not weeks, I'm talking months, obviously, be able to get the data. When we get the information from the DSMB, like we've always done, we will share it publicly.

Jess: What about INT? So you've completed enrollment now for the Phase III for melanoma. When can we hear that data?

Sté**phane:** We completed the enrollment around September. The Phase III started in July 2023. The teams, across the board, with our colleagues at Merck, did a great job to get this done. As you know, we have to manufacture every product for every individual.

If you look at the Phase II data, you started to see separation from the KEYTRUDA-only arm at around 12-plus months. If you just play the calendar forward, 2026, it's tough to be precise on when because, again, it's case driven, but 2026 should be when we get the melanoma Phase III data readout.

As I said, the plant will not be in critical path. The plant could have been on critical path for the potential accelerated approval, but because we're going for full approval now, of course, the plant should not be critical path. We're going to be waiting, like all of you, for the data.

Hopefully, if we get data confirming the Phase II, we will be filing the data with our Merck colleagues as fast as possible and getting the product to patients. Because we think the benefit could be substantial, as you know, the data at the three-year mark, two out of three people have no distant metastases, which, of course, is the leading cause of death is metastasis.

We think this product with no incremental toxicity compared to KEYTRUDA, which people are going to get anyway. When you think about a risk-reward standpoint, you have a product where two out of three people could be three years out with no distant metastasis, with the same tox profile of KEYTRUDA alone. We think that this is a product that is going to benefit a lot of patients. We are eager to get this product to patients as fast as we can.

Jess: What about the other INT trials, for example, the Phase III for lung or...Is there anything that we could learn before we flip the card on the Phase III melanoma trial, anything in '25?

Sté**phane:** Because all those studies have all enrollment curve, and they're all timing to read out, it's hard to predict are we going to get or not additional data from those studies before we see the melanoma Phase III.

Like we've done in the past, when we'll have data, we'll share it at medical conferences. We have done that consistently. At this stage, it's hard to predict precisely when we're going to get those data.

Jess: When you get melanoma, we won't be waiting on manufacturing.

Sté**phane:** No.

Jess: It's all clear.

Sté**phane:** Yes, manufacturing is not a critical path for the launch of melanoma INT.

Jess: One of the products where I think we will get pivotal data this year is norovirus, right?

Sté**phane:** We could. As I said and we said before, because it's a case-based study, if we get the number of cases, we could read out this year. If we don't, we're going to have to go second season. Same thing for the full efficacy study.

Those are all case-driven studies. It depends on the AP and the number of cases happening. That's an event-based study. We will, of course, update the community based on what we learned. It's possible, but it's hard sitting here in early January to know.

Jess: How do you envision the market opportunity for a product like that?

Sté**phane:** We're quite excited about norovirus, and we're excited because we spoke to hospital leaders. We spoke to our retail customers. There's no product on the market. If you think about the target population and you start adding all the layers of the target population, it's actually quite a lot.

You have, of course, the elderly who are hurt by noro, including a long-term care facility, of course. If you think about health care workers, there are a lot of health care workers every year who get sick because of a norovirus infection that they get from one of their patients, either it's a nurse or a doctor. When you think about the number of medical workers in this country and around the world, it's a lot.

Then you have also educators. I'm sure anybody who has young kids or remembers having a young kid, we've seen a couple of times with kids in daycare or in lower grades in kindergarten and so on. That's another population, the educators who are highly motivated, because bringing from work a disease where you get your own family sick in addition to yourself is not fun.

There's, of course, also some other opportunities like cruise ships and other pieces that we've also had discussions there. When you start to add all those numbers, it's actually a pretty large addressable population.

For anybody who's had norovirus disease, it's really not a fun experience to have norovirus. We think that this is a virus that's pretty well known. We think the go-to-market strategy will be for the retail channel.

Again, with the retail channel being very interested to bring more and more vaccination possible for the customers of those pharmacies. We think there's going to be also a lot of drive there to drive their own business. We're quite optimistic about norovirus. Now what we need to see is, of course, the Phase III data.

Jess: What gives you confidence that you'll be successful there?

Sté**phane:** Again, with biology, you always have to be humble. We know that mRNA technology works. We've had some interesting data in terms of seroconversion, neutralizing antibody, T cell and so on in the Phase I/II.

Based on the fact that we've had COVID- and RSV-approved; 2024, we had four Phase III

positive vaccine platform. We think there's a high confidence that this should work, but again, given its biology, given there's a lot of diversity in the type of different strain of norovirus that circulate, we have to be cautious until we see the data.

Jess: Maybe coming back around to RSV. Why will or maybe will not 2024 represent a benchmark for what that market looks like going forward?

Sté**phane:** I think there's a lot of variables or a lot of unknown that public health leaders are trying to navigate as they learn about having new vaccines available for this virus. The virus has been with us, of course, for a long time, but vaccines have been available for only one and a half seasons so far.

What I think you see is what I've been told by some of my colleagues that have been doing vaccine development all their lives is that when you launch a new vaccine, COVID apart, because it was a pandemic, usually takes several cycles of ACIP recommendations to get real-world evidence to fine-tune the recommendations, both on the efficacy, but also, of course, on safety.

We anticipate that as the public health leaders get more and more data, they will fine-tune their recommendations. We're in active discussions with them, as you can imagine.

The piece that is clear is there's still way too many Americans hospitalized every year because of RSV. Some of them lose their lives to RSV. We, collectively with public health leaders, want to work to figure out what's the right frequency of boosting, what's the right use of a product, in which population, comorbidity factors, all those things.

Actually, there's still a lot to be learned. I'm confident that over time, the public health leaders, as they get the data, they want to protect people, will be able to find the right recommendation to protect as many people as we can, but it's going to be a durable franchise because RSV is not going away. And the populations in most countries are getting older pretty fast.

Jess: Maybe speaking of public health leaders, in what way can the new administration and kind of the incoming leadership in some of the public health organizations impact or change how vaccines are developed, approved or recommended, if at all? Does Moderna expect any changes there?

Sté**phane:** It's a bit too early to know exactly what's going to happen and what's going to change and not change. The piece that we are confident is that, I think, every elected leader and every

public health leader in those agencies, CDC, FDA, CMS and so on, want to protect the American people, want to make America healthy again.

Vaccine is a very important tool. If you think about vaccines in the elderly, if a recommendation was to be changed, the impact will be seen in the same season. We actually might see an increase in cost. Just let's look at cost in the same season, because as we know, a 70-year-old person that is hospitalized is going to cost much more that same year by being hospitalized with very high cost.

There are a lot of doctors, scientists in all those agencies that know the fact and will be able to provide to the new elected leaders those facts so that they understand the benefit and the risk-benefit in terms of vaccinations that has been known and demonstrated for a long time.

And so we're going to collaborate with the new administration, like we've always done with every administration in every country where we operate. We believe that focusing on the data and the risk-reward ratio will be the right way to do it.

Jess: Maybe building off of that question, what, if anything, do you think is kind of most misunderstood in the Moderna story right now?

Sté**phane:** How long do you have?

[laughter]

Sté**phane:** If I were to describe to you, let's take the midpoint of this year's range and tell you, there's this new biotech company named X that has two billion dollars of sales, two products approved, nine billion dollars in the bank, just filed three new BLAs and there's potentially six Phase III readouts coming soon. I think most people will say, "Wow, this is pretty cool. This really rarely happens, right?" That's where we are today.

The thing that happened to Moderna that was never in our plans was the pandemic. The pandemic happened. We were an 800 people company. I'm so proud of what the team has achieved to run so hard and work so hard to deliver what we delivered.

One of the two vaccines that got us back to a normal life. Through that, we went from sales to $18 billion in 2021, $18 billion in 2022, and then down to 6 and then 3-ish last year, and we might be again using the midpoint of 2 billion next year.

The proceeds of COVID have first taught us a lot. We've got two products approved. We scaled up manufacturing to literally make billions of doses. We'd made 100,000 doses in 2019. We are focusing on the three priorities I gave you, which is drive sales through existing products, focus on the products that are just in front of us over the next couple of years, to diversify away from COVID to drive sales growth again.

We have the capital to do it. As you see with our actions announced today, we're going to continue to be very disciplined on the cash. We are not shy of partnering. Last year, we did a partnership with Blackstone. We're very thankful for this partnership where they are funding the Phase III efficacy study of flu. Not using shareholder capital to do that. We're diversifying the risk of our portfolio.

We partnered with Merck on cancer because they are a really, really good company in selling oncology products like KEYTRUDA. We have a partner we didn't talk even about with Vertex in lung disease for inhaled mRNA for the kids that don't respond.

People have been worried about the top line, and we're tripping as transparent as we can. Like everybody, we are, for the first time in our careers, learning how to move from pandemic to pandemic. We've done everything perfect now.

We just talked about earlier about we being too rational, about thinking more people will get vaccinated in the high-risk population. We're calibrating the business, but the the science is working.

We have two products approved, three, five products. We're going to get more products coming. I'm really excited about the next few years. I'm really excited about the next few years. It's going to be quite an interesting impact we can have on patients and the value we can create for shareholder as a consequence.

Jess: You have outlined a number of milestones for the company, a lot of clinical events coming out over the next couple of years. If you were to focus the investors in this room on what's the most important thing that's going to bring Moderna to its next upswing...

Sté**phane:** The way I think about the portfolio is through the respiratory franchise, those Phase III costs as mostly behind us, we're going to drive sales growth because when you're going out to COVID, RSV and then COVID flu and flu and then norovirus, again, to the retail channel, you're

going to drive sales growth.

You're going to have incredible manufacturing efficiency in terms of margin because we don't need to build another factory. It's the beauty of a platform, you make a you make a lot of...COVID, and the week after, you can make, in the same room with the same people, a lot of flu, and then the week after, a lot of norovirus. You do it the way you want in terms of mix.

Think about the incremental gross margin of a new product. It's going to be pretty high. The R&D is behind you because you pay for the study. It's all sold by the same team to the same channel. That's what's going to get us back to sales growth first.

Then, the big value inflection point, of course, is INT. If you look at INT and again, the data we had, the three-year survival data is stronger than the two-year survival data. We don't see that often in oncology, I think. Two out of three people benefited from the data in the Phase II study. That is not 5 percent, 10 percent. This is two out of three people. This is a massive clinical impact.

If you think about INT and how the biology works, could we see a world where INT works in quite a number of tumors? We do believe this is why we're investing aggressively across a lot of different trials as you described.

Merck knows a lot about oncology and knows a lot about Keytruda. And so, I don't think they will be investing like this if they did not believe in the mechanism of action of our INT product, being able to individualize to your own T-cell the signature of your own cancer-based biosequencing of your tumor compared to your healthy cells.

We have a lot to learn about INT. Could INT work in monotherapy earlier in disease? It's possible. We've got some interesting anecdotal signal in some of our basket studies in early days without Keytruda. Could that change care? Could you see a world where we've increased diagnostic, earlier detection, you propose to somebody that is in early discovery of a cancer, really early stage stage 1, INT monotherapy with a side effect of a vaccine?

That will transform cancer. Is it going to work? We have to run the studies. If, again, you think not in quarters, but in the next years, a bit like a lot of oncology product have done that have been successful is you start with one indication and you keep increasing. Not everything works.

Oncology is still a very complex disease that we don't understand everything. If I look at the

coming years, how our science work and what we've learned and we'll continue to learn about the mechanism of action of this cancer product, do I think it could become the largest product of Moderna? For sure. I do believe so.

It won't happen next year, but that's the next big catalyst after getting back into sales growth with a short term product. Some of them having already been filed to the FDA.

Jess: Great. Thank you.

Stephane: Thank you.

[applause]
