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EDITED TRANSCRIPT

MRNA.OQ - Q1 2024 Moderna Inc Earnings Call

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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to Moderna's First Quarter 2024 Conference Call. (Operator Instructions) Please be advised, this conference being recorded.

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

Lavina Talukdar - *Moderna, Inc. - Senior VP & Head of IR*

Thank you, Kevin. Good morning, everyone, and thank you for joining us on today's call to discuss Moderna's First Quarter 2024 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 Stéphane Bancel, our Chief Executive Officer; Stephen Hoge, our President; and Jamey Mock, our Chief Financial Officer.

Before we begin, please note, 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.

I will now turn the call over to Stéphane.

Stephane Bancel - *Moderna, Inc. - CEO & Director*

Thanks, Lavina. Good morning or good afternoon, everyone. Thank you for joining us today. I will start with a review of our business. Jayme ill then present our financial results. Stephen will review our late-stage clinical programs, and I will close by sharing our 2024 commercial priorities and major upcoming milestones.

Our COVID vaccine has already impacted hundreds of millions of people. I'm excited by the progress we've made with our pipeline that has the potential to impact many more people.

During the first quarter, we presented substantial clinical progress during our Vaccine Day, with exciting data on EBV, VZV and Norovirus. In addition, along with our partner, Merck, we expanded studies for Individualized Neoantigen Therapy, INT into 3 new indications.

In addition, through ongoing Phase III studies in adjuvant melanoma and adjuvant non-small cell lung cancer, a Phase II/III study has started in neoadjuvant, adjuvant, cutaneous squamous cell carcinoma, another form of skin cancer.

Phase II clinical trials have started in adjuvant bladder and adjuvant kidney cancer. Together, our vaccines and therapeutic portfolio have a potential to impact hundreds of millions of people each year.

I am pleased with our Q1 performance. Since the beginning of the year, we announced 4 important business agreements and collaboration. We entered into a nonexclusive IP out licensing agreement with a leading pharmaceutical company in Japan. The agreement includes an upfront payment and low double-digit royalty to Moderna on net sales of our COVID key products marketed in Japan by this company. It is nice to see a company recognizing our IP and our figures for our license.

Second, we recently announced a contract to provide 4.5 million royalty of COVID-19 vaccine to the Ministry of Health in Brazil. I am very pleased with this partnership as it is the very first time that Moderna works with a broad environment, and we look forward to providing these doses to protect people in Brazil as they go into their winter season.

We announced the project financing program for up to $750 million in funding to Blackstone to further develop our flu program. We also made public our collaboration with OpenAI to use AI as a transformative tool to increase speed and efficiency and ultimately to improve patient outcomes across our business.

Finally, we agreed with Metagenomi to terminate our gene editing collaboration. All rights granted under the collaboration will be returned to Metagenomi. This is a good proof point of Moderna's continually aim to prioritize our investment for our best opportunities to drive returns.

Turning to Q1 financial results. In revenues, we were ahead of our plans at $167 million, reflecting a highly seasonal nature of our respiratory vaccine business. The net growth was $1.2 billion. We ended the quarter with $12.2 billion of cash and investments.

We communicated during our November call, our focus on financial discipline. I am pleased with what the team has achieved with our operating expenses, cost of manufacturing expenses plus cost of R&D expenses plus cost of SG&A expenses were down almost $800 million in Q1 2024 versus Q1 2023. Jamey will elaborate on this in his section.

With that, I will now hand over to Jamey.

James M. Mock - *Moderna, Inc. - CFO*

Thanks, Stéphane, and hello, everyone. Today, I will walk you through our financial performance for the first quarter and provide commentary on our 2024 financial framework.

Let me start with our commercial performance on Slide 8. Net product sales for Q1 were $167 million, down 91% year-over-year, mainly driven by lower sales volumes of our COVID-19 vaccine in regions outside the United States. This decline aligns with the anticipated transition of the COVID-19 vaccine market or it's a seasonal pattern, whereas in the first quarter of 2023, we primarily delivered doses that were deferred from 2022.

Q1 was driven by sales in the U.S. and the Rest of the World, largely Latin America markets. For Q2, we expect about $100 million in sales for a total of approximately $300 million in the first half of 2024. Q2 will include a portion of our recently announced contract with Brazil.

Moving to Slide 9. Net product sales were $167 million, as I just explained. For the first quarter of 2024, our cost of sales was $96 million, which included third-party royalties of $8 million, inventory write-downs of $30 million and $27 million related to unutilized manufacturing capacity and wind out costs.

This resulted in our cost of sales representing 58% of net product sales, up from 43% in the same quarter last year. The increase in cost of sales percentage was primarily due to the lowest level of sales in the quarter. We continue to expect the full year cost of sales to be approximately 35% of product sales. However, due to the strong seasonality of our business, we expect a higher percentage in the first half.

Moving to our R&D efforts. Q1 R&D expenses were $1.1 billion, reflecting a decrease of 6% year-over-year. This reduction was primarily due to the absence of upfront collaboration payments being made this quarter. The upfront payments made in the first quarter of 2023 were related to our strategic collaborations with Generation Bio and Life Edit Therapeutics.

With the Q1 spend of $1.1 billion, we are tracking towards the full year expected spend of approximately $4.5 billion. Q1 SG&A expenses were $274 million, marking a 10% decrease year-over-year. Importantly, this decrease was driven by all functions in SG&A, and it is a result of our strong focus on cost discipline and strategic investments, driving productivity. I will provide additional color on the next page.

We reported an income tax expense of $10 million for the first quarter of 2024 compared to an income tax benefit of $384 million in the same period last year. The shift is primarily due to the continued application of valuation allowance on the majority of our deferred tax assets, which we first established in the third quarter of 2023.

Net loss for the period was $1.2 billion compared to net income of $79 million last year. Diluted loss per share was $3.07 compared to diluted earnings per share of $0.19 in 2023. We ended the first quarter with cash and investments totaling $12.2 billion, down from $13.3 billion at year-end 2023, largely attributable to research and development expenses and operating activities.

Moving to Slide 10. I want to take a moment to elaborate on the efficiencies we are now seeing across the company. As a platform company, we have the opportunity to build a unique operating model. And over the last few years, we have invested purposefully into people, processes and technologies to build foundational capabilities that will allow us to scale efficiently.

First, we ended 2023 with nearly 6,000 employees, up from 1,300 at the end of 2020. Every function scaled capabilities to enable the increasing product launches we expect over the coming years. Additionally, as you know, Moderna has always led with a digital-first mindset. Over the past 3 years, we have nearly doubled our built-for-purpose software applications to digitally enable our teams.

As an example, we recently went live with the newly implemented rebuilt ERP system. SAP S4/Hana is our new digital backbone for all our operational activities. We have used SAP in the past, however, it was built for a research and development-focused company. And now we have implemented an entirely revised version, supporting our end-to-end business processes more effectively and efficiently.

Another example is our rapid adoption of artificial intelligence. Over the past year, we have built over 750 GPTs. One example in the legal space, our contract companion GPT streamlines the task of reviewing and summarizing contracts across the business. With the GPT providing step-by-step guidance to craft a tailored and insightful salary.

This enables any function to extract critical insights on contracts whenever needed, minimizing bottlenecks and freeing up Moderna's legal department to focus on work of higher strategic value, thus enhancing operational efficiency and decision making.

Another example in G&A is a big purchase of paid GPT for all questions around our procurement and payment processes. Instead of our employees having to find and read policies and procedures, they can easily query to GPT. It also saves time for our procurement and payables teams from answering numerous questions.

AI has already been a good chance for win in short period of time. In general, we see the areas helping incredible speed that allows for an unprecedented impact on productivity and many more. We have rolled out a comprehensive training program and are committed to driving this technology breakthrough.

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As a result of these strategic investments in the people, processes and technology, we were able to significantly reduce purchase services and our use of external consultants, which contributed heavily to the 10% year-over-year reduction in SG&A spend. We are also seeing similar benefits in R&D and manufacturing.

In general, we now have a solid foundation with our operating model. As we continue to grow our commercial activities, we will need to further invest, however we will be able to do that more efficiently.

Now let's turn to the 2024 financial framework on Slide 11, which is in line with what I shared on our last earnings call in February. We continue to expect net sales for 2024 of approximately $4 billion, which we think will be a low point as we expect to return to growth in 2025.

Sales in the first half of the year are now expected to be approximately $0.3 billion. We continue to expect cost of sales of approximately 35% of product sales for the full year. For R&D we continue to expect full year expenses to be approximately $4.5 billion, down from $4.8 billion in 2023.

For SG&A, we continue to expect full year expenses to be approximately $1.3 billion down from $1.5 billion in 2023, and we expect taxes to be negligible in 2024 and capital expenditures in 2024 to be approximately $0.9 billion.

Finally, we expect to end 2024 with approximately $9 billion in cash after touching a low point of approximately $8 billion at the end of Q3, due to the seasonality of collections.

Finally, let me also touch on our recently announced project financing deal with Blackstone, which we are excited about. In March, we entered into a development and commercialization funding arrangement, which commits Blackstone to providing us with up to $750 million of funding for our flu program, so that we can strengthen the product label and fulfill our remaining regulatory applications.

Subject to the regulatory approval in the United States, which depends on data from the funded activities, Blackstone will be entitled to receive up to $750 million in sales milestone payments. These milestone payments are contingent upon achieving specified cumulative net sales targets for our future influenza and combination vaccines.

Additionally, Blackstone will earn royalties on applicable net sales at a low single-digit percentage rate. This funding will offset our R&D expenses and is factored into our R&D framework for the year of approximately $4.5 billion. Overall, we are excited that this deal enables us to accelerate the advancement of our pipeline.

And with that, I will now hand the call over to Stephen.

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Jamey. Today, I'll review updates from our clinical programs that were shared during our recent Vaccines Day, as well as new developments in our therapeutics portfolio.

Starting with respiratory vaccines. We shared updates to many of our respiratory programs at Vaccines Day in March. Our RSV vaccine in Canada is undergoing regulatory review in multiple countries. And pending approval, we expect to launch the product in the United States following the June ACIP meeting and recommendations this year.

At Vaccines Day, we shared updates from co-administration studies of RSV, confirming the ability to administer our vaccine and other vaccines given during the respiratory season.

With our flu program, we recently presented data from our Phase III P303 study at ECCMID and continued discussions with regulators globally towards the goal of filing this year. For our next-generation COVID vaccine, mRNA-1283, we have presented positive Phase III safety and immunogenicity data and are engaging with regulators on the path to approval for that product. Our combination flu and COVID vaccine, mRNA-1083 is in Phase III, and we look forward to sharing those clinical data in the current quarter.

Turning now to our leading and other vaccines. As shared at Vaccines Day, we've had -- we've made significant progress in this portfolio. Our CMV vaccine, mRNA-1647, has fully enrolled its Phase III trial, and we have the potential for an interim analysis of efficacy this year. We announced positive Phase I immunogenicity and safety data from our EBV vaccine candidate, mRNA-1189, and we are now advancing towards pivotal trials with that program.

A second therapeutic EBV candidate, mRNA-1195 is in a separate ongoing Phase I study. mRNA-1468, our vaccine against varicella-zoster virus showed strong immunogenicity, including strong T cell responses, and we are preparing to move that program forward towards a pivotal Phase III study as well.

And our HSV vaccine against Herpes simplex mRNA-1608, is now fully enrolled in its Phase I/II study, and we look forward to sharing clinical data updates when that's available. Now rounding out this portfolio, we presented the positive clinical data from our norovirus vaccine candidate, mRNA-1403 and shared that we are advancing that program towards its pivotal Phase III trial.

Turning now to Oncology Therapeutics. We are happy to report our ongoing Phase III studies are enrolling well. We were excited to announce 3 new INT trials, including a randomized Phase II/III study in neoadjuvant, adjuvant cutaneous squamous cell carcinoma; a randomized Phase II trial in adjuvant high-risk muscle invasive bladder cancer; and lastly, a randomized Phase II trial in an adjuvant renal cell carcinoma.

Now recently at AACR, we presented Phase I data from our INT program in advanced unresectable HPV-negative head and neck cancer in the metastatic setting. At AACR, we also presented Phase I translational data from another oncology therapeutic program, mRNA-2752 in various tumor types. Links to both of these presentations are provided on the slide.

Now as a final note, at ASCO, we'll be hosting another Moderna oncology event on the evening of June 3, and we look forward to seeing you there or having you join us virtually.

With that, I'll turn it back over to Stéphane.

Stephane Bancel - *Moderna, Inc. - CEO & Director*

Thank you, Stephen and Jamey. Slide 18 is an overview of our COVID-19 strategy for 2024, which is focused on the need of each 2 region.

In the U.S., our focus is working with public health officials, health care providers and pharmacies to increase vaccination coverage rates. In Europe, we are actively participating in the 2024 tender process. The tender allows for up to 36 million doses per year for up to 4 years. And in the Rest of the World, we have reoriented our commercial teams to prioritize markets for greater commercial focus and impact.

As mentioned earlier, the Brazil contract is an example of how this is working. In the fall of 2023, U.S. COVID vaccination rates lagged behind flu-vaccination rates. U.S. COVID vaccination rates were 11%, with flu vaccination rates at 4x that. And yes, COVID continues to show a higher (inaudible) dieses.

U.S. operation for COVID began October 2023. And last week, we have 424,000 people, which is markedly higher demonstration from either flu or RSV infection. Actually, COVID operations were around the same level as (inaudible) of flu plus RSV combined.

In addition, long COVID continues to be a serious risk to many healthy young adults in their 20s, their 30s, their 40s are losing lung capacity and the mental capacity due to long COVID. The data shows that COVID-19 vaccine reduced the risk of long COVID by 70%.

We believe education and awareness will be very important. We are working on educating consumers about the need for an annual COVID vaccine, just like flu. Too many people are getting hurt when we have safe and effective vaccines available. Our job will not stop until these vaccination numbers come down significantly.

As you know, strength selection by health authorities received approval and launch of COVID vaccine. Health authorities including the WHO and EMA in Europe, have recently selected the JN.1 strain for the 2024-25 formula. The FDA will launch the [real fast] meeting on May 16 to select the strength for the U.S. market.

Moderna has already manufactured JN.1 drug substance to support the potential August launch. We have also prepared for backups in case the FDA does not select JN.1. In 2023, COVID vaccines were available 5 weeks later after 2 vaccines. In the recent channel alone, more than 3 million flu vaccines were administered before the updated COVID vaccines were available.

As we look into the fall 2024 season, we see the potential to align the timing of flu and COVID vaccine approvals. We are encouraged by the earlier (inaudible) meeting for this year's COVID trend selection versus last year. And we're working here and (inaudible) for timely COVID approval. We expect higher vaccination uptake if COVID vaccines are available sooner.

Turning now to the anticipated launch of our second respiratory vaccine, or RSV vaccine, which is expected to launch into a large market. In its first year, the older adult RSV market was $2.5 billion in sales, and analysts expect the older adults' market to grow between $6 billion and $8 billion per year. With marketing application filed in markets globally, we are anticipating approval beginning in the first half of 2024. In the U.S., we're targeting a launch after the June ACIP meeting.

We are very excited to bring a product from a strong differentiated profile to market. Our vaccine has a strong efficacy and safety in clinical trials, and we'll be the only product available in the pre-lled syringe or PFS presentation.

Let me now double-click on what we believe are the benefit of PFS. We recently published a time and motion study that shows faster preparation time for PFS relative to vaccines that require constitution. We call that both RSV combination vaccines on the market require multiple steps to prepare their vaccines for administration.

One vaccine requires process and the overall next steps to prepare. Our PFS presentation is ready to use vaccine straight out of the box. The study from the PFS presentation to be 3x to 4x more efficient as measured by preparation time. Details from the study can be found through the link on the slide.

We believe our PFS presentation for RSV vaccine has the potential to ease the personal burden on pharmacies during the fall respiratory season. The pharmacy chains (inaudible) independent pharmacies and we're looking forward to the launch.

Let me close with major upcoming pipeline milestones. While we're excited about the commercial prospects for the year, we're even more excited about the upcoming pipeline milestone and the effect they will have on our commercial outlook for the next several years serving patients.

In respiratory vaccines, we are eagerly awaiting the approval of RSV and the (inaudible). We are also waiting for data for RSV in the age group 18 and above. We are in discussion with regulators on our flu program and intend to file in 2024. We won next-gen COVID vaccine and on (inaudible), we are pleased with a positive Phase III immunogenicity data and are engaging with regulators. Our flu plus COVID vaccine combo should get this Phase III data soon.

In latent with CMV fully enrolled and at current cases, we look forward to potential for Phase III data efficacy data in 2024. In our INT program, we're looking forward to completion of enrollment for Phase III adjuvant melanoma study. In addition, we are keen to discuss the possibility of accelerated approval with regulators based on Phase II study data.

As we shared before, there are 3 things we view as necessary before we could consider pursuing fed approval for INT. First, durability data from our Phase II study, which we announced in December last year; second, a substantially enrolled Phase III adjuvant melanoma study; and third, manufacturing readiness at the Marlborough site. And last but not the least, our revenue portfolio, we look forward to initiating pivotal study for PMMA.

This milestone will represent continued progress towards our mission to deliver the greatest possible impact to people for mRNA medicines. And asModerna, we are dedicated to achieving them all. Every data continues to confirm the power of our platform and its breadth in the service of patients. Two important save a date for your calendars. We will discuss our COVID program in Chicago on June 1, and our annual R&D Day will be held in New York the morning of September 1.

Thank you for listening, and we look forward to taking your questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Salveen Richter with Goldman Sachs.

Salveen Jaswal Richter - *Goldman Sachs Group, Inc., Research Division - VP*

Firstly, could you discuss your strategy for pursuing contracts for the RSV vaccine given 2 approved vaccine sort of have a head start, timing-wise? And help us understand, as you've communicated with large retail pharmacy, how significant the PFS formulation is to them?

And then secondly, with regard to moving into the 3 new indications for the INT program. Maybe help us understand signals or specific data points that support that?

Stephane Bancel - *Moderna, Inc. - CEO & Director*

On the RSV contract. So as you know, we are not allowed to contract until the product is approved by the regulators. But what we are doing, because we can do that, is our medical teams are actively engaged with retail pharmacies, but also IV and hospital networks in terms of making sure the data on the efficacy profile of the product, on safety, and of course, in the PFS and the benefit of PFS in terms of productivity. Those discussions are ongoing literally on a daily basis, including with leadership of those pharmacies. And the next step, of course, is to wait for the FDA approval. Stephen?

Stephen Hoge - *Moderna, Inc. - President*

Yes, sure. So thanks for the question. So on the 3 additional INT indications, I think the short version of it is they are all adjuvant settings. Similar to our melanoma Phase II results have been so encouraging, where KEYTRUDA has a known benefit and where we still believe that there's an opportunity to improve on that by driving a specific T cell response with INT.

And so as you know, in Phase I, we looked across a range of different indications. That was more in the metastatic setting. But as we've announced since we first saw that positive Phase II results from melanoma, we have been aggressively pursuing adjuvant indications where IO is approved and where we see an opportunity. And all 3 of these fits squarely in that space.

Operator

Our next question comes from Michael Yee with Jefferies.

Michael Jonathan Yee - *Jefferies LLC, Research Division - MD & Senior Biotechnology Analyst*

Two questions as well. On RSV, I guess, the competitor GSK as well this week was commenting about how they're expecting you to be in the mix and contracting is ongoing. I know you have some RSV in your guidance. I think the math implies maybe hundreds of millions of dollars. Can you just perhaps comment on how you adjusted, or probability adjusted or thought about how much is there in your guidance and your confidence on that for this year?

And then secondly, on INT as well. I know you had some data at ASCO. I know you have breakthrough therapy and prime designation. How important is the Phase III enrollment progress, the confirmatory study? I feel like that's always an important discussion with FDA. So how important is that progress before you can really engage with FDA?

James M. Mock - *Moderna, Inc. - CFO*

Yes. Maybe I'll take the first one. Thanks, Mike, for the question.

So as you may know, we haven't guided any specific guidance or number for RSV. In the past, we did break down the $4 billion into 3 different segments around the U.S. market, the APAs we walked into the year with and then another category of other COVID sales that didn't have any APAs across the rest of the world, a good example is Brazil that we just signed, as well as RSV. So no specific guidance for RSV from a financial perspective.

Stephen Hoge - *Moderna, Inc. - President*

And your question on INT. I think you nailed it, it's a really important topic, and in particular right now, as we think about accelerated approval that we demonstrate the diligence and substantially enroll the confirmatory study. So really all you're waiting for is for that study to mature, it could be several years.

We think it's really important. To be fair, we have not consulted with the agency on that yet. As we've said, we're waiting until we crossed our own threshold. And also at this point, until we've established the manufacturing facility with that line of sight to that.

But we do feel that, as we've said, substantial enrollment demonstrating that essentially all you're waiting for is the readout on that confirmatory study is our obligation before we even want to go forward with that question.

We are making great progress this year, and we're optimistic that both that and the facility will be available in short order. And then, of course, we'll want to start engaging with our data, including the FDA on the question of accelerated approval.

Operator

Our next question comes from Terence Flynn with Morgan Stanley.

Terence C. Flynn - *Morgan Stanley, Research Division - Equity Analyst*

Great. Maybe two parts for me. Just on the RSV vaccine. Can you provide your latest perspective on what the most likely ACIP recommendation will be? Will you get a parity recommendation to the competitors? Or do you think there's a potential for a differential recommendation here?

And then just wondering any update on your ongoing conversations regarding filing your seasonal flu vaccine? I know you mentioned in your prepared remarks, but just any more insight in terms of what the gating steps are here.

Unidentified Company Representative

Thanks for both questions. So first on RSV, caveat by saying we have to complete the approval process with FDA. And then at the end of the day, the recommendation really falls to ACIP and the committee members, so I defer to them.

Our expectation, our hope is that when they review the data package that we already have as well as additional data that we expect to be able to share at the ACIP meeting on durability through a second season, on immunogenicity across other populations, we expect a parity recommendation. We certainly think the data supports that. But again, I'll defer to the committee members on the ultimate decision.

Stephen Hoge - *Moderna, Inc. - President*

On the question of flu, we are actively engaged right now on the -- with regulators on the process for submission of the flu vaccine. As I mentioned a moment ago, we are also closing in on clinical data from our combination flu COVID vaccine, mRNA-1083. And that obviously has an important role in our engagement with regulators, generally on flu versus flu COVID combination.

And so those discussions are ongoing. I won't provide any other update on it except to say, as we've said today, and we will continue to say we expect to file the flu product this year, but it will be dependent upon a number of considerations plus we also including the (inaudible) data that we expect to see soon.

Operator

Our next question comes from Eli Merle with UBS.

Eliana Rachel Merle - *UBS Investment Bank, Research Division - Analyst*

On CMV, how are you thinking about the need or benefits of potentially boosting both from a clinical as well as a commercial perspective? And if you would study those? And then second, just on CMV, if you don't meet the interim, the analysis there, would you disclose that?

Stephen Hoge - *Moderna, Inc. - President*

So first, on the question of boosting. So far, what we have -- we obviously don't have the efficacy readout. That's the Phase III study is ongoing. But we do expect to have quite substantial durability data on immunogenicity. And it's quite possible that the efficacy data will give us a signal what the core of production could be.

And so we don't, right now, have any evidence they're not good, durable, multiyear, possibly as long as 5 years, we continue to track the immunogenicity protection. It's possible that will extend out to 10 years and then some boosting is necessary. It's also possible that we decide that a booster might be necessary shorter term in that, let's say, 5 years or 10 years.

We just don't know at this time. And so at present, the data we do have on the durability of the immunogenicity, it looks quite strong. And so we do think our 3-dose series will likely be protective for a very long period of time, all subject to the efficacy data that you just referenced.

So on the interim analysis for efficacy, as we've said before, we're making great progress in that study in accruing cases, and we do expect to be able to provide an update on -- or conduct at least an initial interim efficacy analysis this year.

Because of the rate of case accrual and also because the protocol calls for us to cross a median of 1-year follow-up, the timing may be sets -- by the time we get to that first interim analysis, we are also have enough cases for a final analysis or that a final analysis is imminent. Let's say, it's a very short period of time away.

And so because of that uncertainty, until we see that data and understand how close we are to that final analysis, I don't think we can commit, one way or the other, whether we're going to be updating, it will really depend upon the data we see and then how quickly we expect to get that final analysis.

At the end of the day, if we have news to share both on interim and the final, we, of course, will, but I don't think we can commit at this stage because we haven't seen the data yet.

Operator

Our next question comes from Hartaj Singh with Oppenheimer.

Hartaj Singh - *Oppenheimer & Co. Inc., Research Division - Research Analyst*

Great. I just have a question on -- you're developing a refrigerator stable vaccine and flu vaccine, I believe. And I'd just like to kind of understand how you think about that. When could that get approved? And then will the combo vaccine also be refrigerator stable?

Stephen Hoge - *Moderna, Inc. - President*

Great. (inaudible)

Operator

(technical difficulty) Ladies and gentlemen, please stand by, your conference will resume momentarily. Once again, ladies and gentlemen, please stay on the line.

And pardon me, can you all hear me now? Could you try speaking again? Your line was muted.

Unidentified Company Representative

Yes, I'm here. Can you hear me?

Operator

Yes, we can hear you now. So your line got muted, but you can go ahead and continue.

Stephen Hoge - *Moderna, Inc. - President*

Right. Sorry for that brief interruption. So Hartaj, thank you for the question. Just to quickly restate what I was saying. The -- all of our respiratory portfolio, RSV, flu, COVID and the flu COVID combo are being developed towards refrigerator stable PFS. And so our mRNA-1083 program, the flu COVID program as well as the flu program are intended to be a refrigerator stable prefilled syringes. As Stéphane mentioned a moment ago, we really view that as the ideal presentation, the helpful presentation for health care providers really around the world to facilitate their delivery of the vaccine to patients.

Operator

Our next question comes from Gena Wang with Barclays.

Huidong Wang - *Barclays Bank PLC, Research Division - Research Analyst*

I have two. One is regarding COVID. So for the EU, you said up to 36 million doses every year in EU. What could be the scenario you can get 36 million doses in EU? And also the price in Brazil and the EU, should we use pandemic price of $25 to $30 per doses at the benchmark?

Quickly on R&D, accelerated approval path. Based on, say, today's comments and the prior discussion, our impression is you could achieve all the 3 key components by the end of this year. Is Merck is also fully on board to submit for the accelerated approval in melanoma?

Stephane Bancel - *Moderna, Inc. - CEO & Director*

Gena. It's Stéphane. I'll take the COVID question and then Stephen will talk about INT. So the tender is up to 36 million doses, will depend on a number of countries that apply to the tender through the EU. So this, we'll know at the end of the process. And as it's a tender process so there is no dialogue, we're just entering all the files and all the data, and that's really ongoing. The team is obviously very active on it.

And on price, for obvious competitive reasons, we're not going to share price in any market to -- because competitors will know the price right away. Stephen, INT?

Stephen Hoge - *Moderna, Inc. - President*

Yes. So we haven't specifically guided to when we expect to complete, obviously, the second and third parts of our 3-part criteria. That being manufacturing readiness, as you can imagine, work is going on around the clock as well as the enrollment we've made great progress, but we have to sustain that progress.

On your question of where is Merck on this. I think you'll have to direct it to them. Our view is that if we're able to get to the point where ancillary approval is appropriate and regulators are supportive of that, we can't imagine why ourselves and Merck wouldn't want to make the product available to help people suffering from cancer right now.

But the contingencies, there are, obviously, we have to do our work and our doses this year. And then ultimately, we have to speak to regulators, and they get to decide whether that pathway is available to us. And so I think for both ourselves and our partner Merck, we want to defer to regulators ultimately on that choice.

Operator

Our next question comes from Luca Issi with RBC Capital.

Luca Issi - *RBC Capital Markets, Research Division - Research Analyst*

Maybe a very quick one on RSV. I think the last press release actually cited May 12 as the PDUFA date. While today, you're simply saying the initial regulatory approvals in the first half of '24. So is there anything to read to it? Can you just confirm that the PDUFA date is still May 12, which is actually the end of next week?

And then maybe second, on IP, can you just comment on the recent decision by Judge Goldberg to rule out, obviously, (inaudible) or you're looking on a particle. Our understanding, this can have pretty material impact on both prior and future sales of COVID. So again, any thoughts there, much appreciated.

And then super quickly on INT. Stephen, what's holding you back on starting the randomized trial intended to cancer into metastatic static? I thought the data they see that was pretty impressive. So any thoughts there, much appreciated.

Stephen Hoge - *Moderna, Inc. - President*

Great. Perfect question. I'll take this first from the third very quickly. So on the function of RSV, we continue working towards the same PDUFA date, and there's no change to that. As you know, there's a lot of work and around the clock work by ourselves, obviously, and folks at the agency.

And so we're hopeful that, that happens as planned, but if it takes a little bit longer, at the end of the day, what really matters is the duty for (inaudible) meeting, but there's been no change to report. So don't read anything into that.

As far as the INT question, on head and neck, I appreciate the question because we are also obviously enthusiastic about that data. However, our partner, Merck and ourselves, we have not yet decided where that fits in the priority of other indications, pathologies and opportunities we're pursuing.

As you've already seen in the past year, we've stood up a very large number of study. And we're just trying to pace ourselves. And so it will take us a little bit of time with our partner, Merck, to determine what the next steps are in head and neck. And at this point, we do not have an update on.

Stephane Bancel - *Moderna, Inc. - CEO & Director*

And I'll take the IP questions. I mean as you know, our COVID-19 vaccine technology, including our lipid nanoparticle delivery system is the result of independent research and development. We have a strong belief that our technology does not impact on the patent asserted by (inaudible). We are confident in our position, and we look forward to presenting our case after next year.

Operator

Our next question comes from Jessica Fye with JPMorgan.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

I had a few here. So for INT, I know you mentioned you can't comment on when you expect to complete the manufacturing scale up. But can you provide a status update on where you stand with that today, and the number of patients you can support right now as well as where you want to take that capacity once you get to the end of this 3-phase scale-up process, even if you don't put a timeline on when you'll get there?

Next one is coming back to flu. Can you just refine a little bit when the 1083 immunogenicity data will be available? And maybe elaborate on how the combo data play a role in the regulatory talks on 1010. I thought you previously said these products could stand on their own. And that you might not need 1010 approved to get 1083 approval. So now wondering kind of why 1083 might factor in for 1010.

And then lastly, on CMV, can you remind me how the risk of CMV and pregnancy compares in seropositive versus seronegative individuals. I'm thinking from a commercial standpoint, how you weigh the strategy of pursuing vaccinating everyone versus just seronegative people.

Stephane Bancel - *Moderna, Inc. - CEO & Director*

Great. I'll start with the INT question on manufacturing, then Stephen can add around (inaudible). So we have not provided some capacity numbers of the factory in Marlborough. But of course, as you can assume, we now the size of melanoma market. And we know our stronger data. We (inaudible) people benefiting from the Phase II data.

So we've sized the plant accordingly, as you can imagine. But also, we are building the plant for care because, as you know, Stephen and his team and his colleagues are running a lot of studies. So this is not a platform in (inaudible) a plant for INT. Again, from a manufacturing standpoint, we don't care which cancer is in terms of organ because we use genetic information to design an individual product for every human being.

So basically, we bought a plant last year that was kind of -- is a big building finished, saves us time to market. Obviously, we don't have to get the permitting and build the building. And so the team since then, that is now more than a year ago, has been working actively to get the plant ready.

And the plant is on the building in modules inside the building. So basically, we're going to launch with the first module of manufacturing capacity. And then -- and one day maybe we do an opening of a facility like we did for (inaudible). You will see that there's another empty space left behind, which has also a very quick ramp-up because the HVAC system and all utility system has been set up for the entire plant. And so then you just add modules as you go. So we'll be able to scale very quickly as we get more indication available.

But again, we're aware of the melanoma number of cases. And so the plant will be sized so we make sure we can provide products to patients. Stephen?

Stephen Hoge - *Moderna, Inc. - President*

Thank you for the clarifying question on flu. So let me just start by saying that independently, we are looking to submit both the flu program and the flu COVID combo program. So that's 1010 and 1083. Obviously, we need to see the 1083 data, and we'll announce that when we have it.

The question on the timing of that data, it's imminent. And so in the coming quarter, we expect to be able to share that update. The point about interdependency, I suppose, is just more about sequencing of those submissions and in some places and some regulatory geographies, obviously, you can't stack them on the same day if you will. There's a logical sequence.

And what we want to assess once we see the 1083 data is our regulatory strategy as well as our preparation and delivery of data for the submissions to determine which one will go first or second. But at this point, we're trying hard to make sure that we can do both products across all of our major markets, if the data is filed in this year.

And so we'll go more on that as we move forward. But for now, we are proceeding without independently. Sorry for the confusion model.

On the question of CMV and seropositivity. So it's a really important point. Thank you for raising it. But while the majority -- well, the risk of vertical transmission of CMV to pregnancy to the fetus is highest in seronegative. It does happen in seropositives as well. So congenital CMV is a disease that's seen in -- particularly in reactivation or sometimes reinfection, even in the seropositive context. And so we do believe that there's a potential for benefit for a vaccine even in seropositive population.

We are evaluating the study right now in seronegative because the rate of that transmission and obviously, the potential to prevent against infection is more enriched and therefore the study size, primary are focused on seronegatives.

But we are looking. We have studied the vaccine from a safety perspective in seropositives. And we are looking at things like [Sheng]. If you draw a little bit of an analogy to correlate to the EVB data that we've already put out there in a different virus, but we've been able to show that we can really control the rate setting even in seropositives (inaudible) qualifiers.

And so we have some reasons for optimism and believe that when we pull together the totality of the data, there will both be the obvious potential benefit, which is that there is still vertical transmission in seropositives and some -- potentially some data on the rate of (inaudible) that would be supportive to that.

Ultimately, though, we're studying all the way down to 16-year-olds. And our goal will be a label that 16 plus, with the goal going into a population that is not as highly seropositive as it is later in life and therefore, we see a very large opportunity, improvement, and then primary infection CMV with the vaccine and the potential for (inaudible) seropositives (inaudible).

Operator

Our next question comes from Geoff Meacham with BofA.

Alexandria Hammond - *BofA Securities, Research Division - Associate*

This is Alex Hammond for Geoff Meacham. So on your [zoster] vaccine candidate, when should we receive updates on your pivotal strategy? And is there any color you can provide today in terms of your current thinking on the Phase III design?

And then our second question is on the PA and MMA programs that are advancing into pivotal trials, can you provide any thoughts on the nature of editorial and the comments on safety?

Stephen Hoge - *Moderna, Inc. - President*

Yes. Could you describe about the first part of the question was on which program? The zoster?

Alexandria Hammond - *BofA Securities, Research Division - Associate*

The zoster, the shingle.

Stephen Hoge - *Moderna, Inc. - President*

Shingle zoster. So on the (inaudible) program, we have -- we're obviously very excited by the Phase I data, which was compared against a licensed product, and we saw really strong T cell response in immunogenicity. And generally, we've been in that across our programs. But in that one, it was very encouraging.

We're in the process right now of trying to find the pivotal strategy. That will include, obviously, dose selection, the number of doses in that study and then how we're going to expect that study.

We do not have an update till today on what that will look like in addition to our own thoughts on it, we obviously want to consult with regulators before we finalize that (inaudible). But we are moving for forward -- towards a pivotal study in PCV. We do not have a (inaudible) on that update yet.

As it relates to MMA and PA, the clinical data that we have continues to show a compelling benefit risk profile, good safety profile. In fact, in the PA studies, we have many folks who've been in those -- in the study on drug for well over a year. And over 30 years, I think, from our last update in overall patient dosing experience.

So we are starting to get a very clear perspective on the safety profile. The editorial question, I don't have a view on editorials or opinions based on the preclinical data. I think we stand behind the clinical data that we have and are quite encouraged by that profile, and we'll continue to watch it closely in our ongoing Phase I studies, but we do not have any specific or new concerns based on the clinical data today.

Operator

Our next question comes from Evan Wang with Guggenheim Securities.

Boran Wang - *Guggenheim Securities, LLC, Research Division - Healthcare Equity Research Analyst*

Two for me. First, on the combo 1083 program, so data, it sounds like this quarter, I believe enrollment was completed a few months ago. So I guess how comprehensive will the top line update be in terms of follow-up? And then with submission, is longer-term vault needed there? And are there parallels from 1010 that we can take in terms of regulatory filing speed for 1083? Or is that more impacted by the decision for buying one or the other first?

And then second, on RSV, it's kind of early ahead of approval, but with some international markets, it seems that's more nascent in terms of established some reimbursement there. So I guess how are you thinking about positioning internationally?

Stephen Hoge - *Moderna, Inc. - President*

Great. So for the 1083 data, yes, on this quarter, and I would say that we're -- we enrolled the majority of the 1083 studies you know last fall. And the 1010 second-generation study. So we talked about the P303 study. The first part of that enrolled over last summer, just a few months before the combo study.

And the second part of it, there was a part B and C, as you know, looking head-to-head against (inaudible), that actually enrolled the same time as the 1083 study last fall. And so they've been actually kind of tracking right on top of each other.

I think we're going to wait to see the data before we can provide growth guidance on timing. But obviously, we're -- we've been working towards that flu COVID combination product for a while, and we will want to make sure that we get that filed, if it is positive as fast as possible.

I wouldn't draw too many, because of the difference in the structures of the study between the P303 study, which has a part A and the B and a C, and the 1083 study, which was done very quickly. I wouldn't draw too many correlations between (inaudible) reading out and the timing for submission on (inaudible).

Stéphane, do you want to take the RSV question?

Stephane Bancel - *Moderna, Inc. - CEO & Director*

Sure. So with internal markets, obviously, very important, the U.S. is very important, the U.S. and Russia also super important. As we shared before, we found in all the major geographies already. Of course, EU, U.K., Canada, Australia, some countries in Asia, some countries in the Middle East.

RSV is well known by public health leaders like it is in the U.S. So I think that there's a very strong desire, again, to protect the elderly or what we are doing here in terms of true COVID RSV, that's becoming very kind of a standard that probably (inaudible) across at least the developed world. But even in developing countries, there's more and more interest as you see aging population everywhere.

So it's not only the U.S. approval that we expect coming soon is we have several geographies that would start being approved so.

Operator

Our next question comes from Simon Baker with Redburn Atlantic.

Simon P. Baker - *Redburn (Europe) Limited, Research Division - Head of Pharmaceutical Research*

Two quick ones, if I may. Just in terms of the timing on the CMV interim data. You said this quarter, it could be as early as the end of '24. That sounds slightly later than you previously said. I just wondered if that's me over-interpreting the semantics or whether there is a slight delay there?

And then the second question is on the HSV vaccine. Previous quarters, we talked about the EBV vaccine and the potential utility in multiple sclerosis. So I just wondered what your thoughts were about HSV and it's the hypothesis that implicates it's role in Alzheimer's disease?

Stephen Hoge - *Moderna, Inc. - President*

So first on the clarification. There's no change to our expectations on when the CMV readout will happen. I think we previously tried to be careful in saying that we expect it to happen this year. And so obviously, by the end of this year, it is meant to say the same thing, but there's no change in our expectations at this point.

On the HSV Alzheimer's hypothesis, it's a very interesting -- there's a lot of neuroinflammatory questions that go with the herpes simplex virus infection across a range of different mutations, Alzheimer's one of them.

At this point, the studies that we expect to move forward with HSV will be for seropositive to improve outcomes. So shedding days, for instance, or lesion based, and then eventually, we will want to consider whether we want to go at prevention of infection, which is obviously a different standard of different indication. That might be more relevant for them, how you think about some of the neuroinflammatory or long-term supply.

I think you asked my opinion on the -- I think it's incredibly interesting and exciting. I do think it's early for us to start drawing connection from a vaccine perspective in terms of our potential impact for it. I hope over time, there is an opportunity to intervene and things like that.

Obviously, in the EBV vaccine with multiple sclerosis, that science has firmed up to the point where there's reasonably high conviction that there's a potential for benefit there. We have to go prove that. But at this point, it's still earlier days, I think, with HSV and Alzheimer's.

Operator

Our next question comes from Edward Tenthoff with Piper Sandler.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Congrats on everything. Actually, most of my questions have been answered. But I wanted to ask with respect to the cancer efforts, are you able to break out what the actual R&D cost is for that program and that's still a cause some profit share with Merck? And how many indications do you guys ultimately plan on pursuing?

Stephen Hoge - *Moderna, Inc. - President*

Maybe I'll take the first one, Ed. So we obviously know what we're spending, (inaudible) but at this point, that we are not prepared to disclose. So maybe someday, but not at this time.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Understood. And then -- with the expansion...

Stephen Hoge - *Moderna, Inc. - President*

Yes. On the expansion indication. Look, at the joint decision, our partnership with Merck has been really strong. We've been building this out. We do like to review those strategically and then bring them forward once we've started them. And so I don't want to get ahead of that because those are our private strategic competition with Merck. But we are not done yet. We will keep adding in the years ahead.

Edward Andrew Tenthoff - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

Very exciting. Look forward to seeing you in Chicago.

Operator

Ladies and gentlemen, this does conclude the Q&A portion of today's conference. I'd like to turn the call back over to Stéphane for any closing remarks.

Stephane Bancel - *Moderna, Inc. - CEO & Director*

Well, thank you, everybody, for joining in today for a great session. We look forward to seeing you at latest ASCO. Have a great day.

Operator

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