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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to Moderna's First Quarter 2023 Conference Call. (Operator Instructions) Please be advised today's conference is being recorded.

I would now like to hand the conference over to your speaker today, Lavina Talukdar. 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 2023 Financial Results and Business Update. You can access the press release issued this morning as well as the slides that we'll be reviewing by going to the Investors Section of our website.

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

Before we begin, please note that this conference call will include forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Please see Slide 2 of the accompanying presentation and our SEC filings for important risk factors that could cause our actual performance and results to differ materially from those expressed or implied in these forward-looking statements.

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

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

Thank you, Lavina. Good morning or good afternoon, everyone. Today, I will start with a business review Stephen will then review our clinical programs before Arpa gives an update on our commercial progress and plans. Jamey will present our financial results, and I will come back to close.

So in the first quarter, we recorded revenues of $1.9 billion, GAAP net income of $79 million and GAAP diluted earnings per share of $0.19. Cash and cash investments of $16.4 billion at the end of the quarter. We continued in Q1, executing on our capital allocation strategy, prioritizing investments in our business. In the first quarter, we invested $1.1 billion in R&D, continuing investment in late stage clinical programs and progressing by entire pipeline.

SG&A costs were approximately $400 million in the quarter, which include investments in digital and also AI infrastructure and approximately $100 million in capital investments. In 2023, our (inaudible) team has been very active. This includes the acquisition of OriCiro in Japan, collaboration with CytomX, Life Edit and Generation Bio. All of these investment opportunities further expand the reach of Moderna's mRNA technology.

We are growing Moderna mRNA operating system. $526 million were returned to shareholders with share purchase of 3.6 million shares in the quarter. Let me turn to Commercial in the first quarter.

We continue to expect $5 billion in COVID vaccine deliveries in 2023 from already signed advanced purchase agreements. With $1.8 billion of COVID sales in Q1, we are well on our way to achieve $5 billion in APS. The commercial team is actively negotiating to sign new contracts with customers in major markets to finalize additional orders that will add to the $5 billion. The U.S. team is negotiating with pharmacy chains, hospital networks and other customers.

As a reminder, the $5 billion of signed APAs does not include any fall of 2023 U.S. contracts. So these new U.S. commercial contracts are important to the business as they are additional. The team is also making progress in Japan, in Europe and other countries in Asia, Middle East and also Latin America. We recently signed a new contract in Australia for 2023. Our commercial organization is also preparing for the launch of RSV in 2024. Our next respiratory commercial products. They're educating the medical community on the health burden of RSV. Our medical team is participating in major infectious disease medical congresses and sharing the new data that shows a strong profile of our RSV vaccine. To prepare for our RSV launch, our manufacturing team has already begun producing drug substance, the mRNA molecule for RSV vaccine. The vaccine will be supplied as a prefilled syringe. We believe that will help drive adoption by pharmacists and doctors versus some of our RSV products.

In oncology, for mRNA-4157 now called individualized neoantigen therapy, or INT, we are scaling up manufacturing to support clinical development and commercial markets. Our commercial team is also working to prioritize tumor types to select for additional Phase III studies in addition to melanoma and lung.

Turning to the pipeline. At Vaccine Day, we discuss detailed data from our RSV vaccine that were presented at RSVVW medical meetings. We believe the profile of RSV vaccine is potentially best-in-class. We shared top line data on the 2 programs announcing the initiation of Phase 303, the Phase III study that we intend to use for accelerated approval as well as strategy for our next-generation Flu programs. We also announced the start of Phase III for next-gen COVID vaccine, mRNA-1283, which should be refrigerator-stable.

Today, we're also announcing a new program for pandemic readiness for Influenza H5. In latent vaccine, our CMV Phase III trial continued progress and is greater than 50% enrolled. I'm also very pleased to announce progress in our early-stage program, EBV and HIV. EBV, as you know, has 2 programs. The EBV Phase I trials to prevent mononucleosis with mRNA-1189 are fully enrolled in adults and also in adolescents. Our EBV trial for the treatment of long-term complication for EBV infection has now started enrolling. And for HIV, we shall interim analysis from our Phase I study at Vaccines Day.

We also introduced new programs. We are working on vaccines for Norovirus and Lyme Disease. Lyme is the first bacterial pathogen we are targeting with mRNA platform (inaudible) vaccine. In Therapeutics, we participated in AACR meeting where we presented detailed Phase II data from our INT program partnered with Merck. Later on the call, Stephen will take you through the data presented there.

Already this pipeline is also making progress. We're excited to announce a new milestone for our PA program. The Phase I/II trial in propionic acidemia or PA, is now in dose expansion phase. And additional data from this study will be presented at the American Society for Gene and Cell Therapy later this month in May.

The company continues to expand at a rapid pace. We have 47 programs underway which now reflects the inclusion of new program (inaudible) in the quarter and removes programs that are not continuing to develop. The full of these pipeline can be seen in the appendix of this presentation or obviously on our website. We now have more than 4,000 team members and 17 commercial subsidiaries across Americas, Europe and Asia Pacific.

In addition to our commercial subsidiaries, we also announced we're opening a Seattle office as a technology hub, where we're hiring the data scientists and engineers who will help digitize our business and expand our AI capabilities. I'm also happy to announce Moderna was officially recognized in March has a Great Place To Work by the Great Place To Work Institute. Our $16.4 billion of cash at the other quarter is enabling us to scale across our research, development, manufacturing, commercial and G&A.

With that introduction, let me now turn to Stephen.

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Stephane. Good morning or good afternoon, everyone. Today, I'll review the clinical progress in R&D at Moderna in the first quarter and highlight select data from the past few months has been presented. The core of our respiratory portfolio is made up of vaccines against COVID-19, flu and RSV, which are either commercial or in Phase III. We're advancing second-generation vaccines, this includes our second-generation refrigerator stable COVID-19 vaccine candidate, mRNA-1283, which is rapidly enrolling in its Phase III study and 2 next-generation influenza vaccines that are in Phase II. We believe combination vaccines will be the future of our respiratory franchise. And we're pleased that we now have 5 different combination vaccine candidates in early clinical trials, including 2 specifically designed for pediatric populations.

With 11 programs in clinical trials, including 4 in Phase III and covering 5 different respiratory viruses, we believe this represents the broadest and most advanced portfolio of respiratory virus vaccine candidates. Now turning specifically to COVID.

The FDA recently provided updates on several fronts. Our Omicron-targeting bivalent COVID-19 vaccine targeting the original and BA.4/5 strains is now our only authorized formulation in the United States with a simplified and streamlined regimen for both children and adults. Individuals, 65 years of age and those with certain kinds of immunocompromise are now also eligible to receive additional doses as needed or recommended by their physicians.

As we look to the fall, the strain selection for an updated composition for fall 2023 boosters is now expected to come at the June 15 VRBPAC meeting. Moving to RSV.

We're pleased by the profile of our vaccine in older adults with high and consistent efficacy against RSV lower respiratory tract disease across populations in our large Phase III study. At 2 recent medical meetings, we've shared data showing our vaccine's efficacy was consistently high across all age groups, including in the oldest adult and in participants with preexisting comorbidities that put them at higher risk.

mRNA-1345 has also shown a favorable tolerability profile with AEs mostly grade 1 or grade 2, mild to moderate. As we shared during Vaccines Day, today, we have not seen any cases of Guillain-Barré syndrome or other severe demyelinating events in the trial.

Moving to flu. Our Phase III efficacy study in the Northern Hemisphere, P302 is ongoing. And last month, we announced that the study did not accrue sufficient cases to declare early success at the interim analysis and that the DSMB recommended that we continue the study. That trial is still accruing cases through the end of this flu season with an update expected this summer.

The preliminary immunogenicity data from that P302 study showed that HAI neutralizing titers were consistent with superiority for both A strains and non-inferior immunogenicity for the B strains when compared to the licensed flu vaccine. Now I'm pleased to announce that we've initiated our Phase III P303 flu study with an updated formulation of mRNA-1010. P303 is testing an update that is designed to increase the HAI neutralizing titers against the B antigens. This is an immunogenicity study and is expected to enroll approximately 2,400 adults this spring. We believe this study will support our initial flu filing and the potential for a 2024 launch if approved by regulators.

Now turning to our latent vaccines. Our CMV vaccine Phase III study in women and childbearing age is ongoing and has enrolled more than 50% of participants. We also have an ongoing Phase I/II adolescent dose-ranging study with this vaccine that will expand potential eligible populations. As Stephane mentioned earlier, we continue to make significant progress against all of our latent vaccines in earlier-stage clinical trials, including candidates against EBV, HIV and VZV. As Stephane mentioned, our EBV vaccine includes 2 vaccine candidates, our EBV program includes 2 vaccine candidates mRNA-1189 and mRNA-1195 and are in clinical trials for prevention of infectious mononucleosis and for the prevention of longer-term sequelae of EBV infection respectively.

Now at Vaccines Day, we are pleased to share interim results of our HIV vaccine, mRNA-1644, which continues to advance. Our pipeline in therapeutics targets unmet needs across immuno-oncology, rare disease, cardiovascular disease and autoimmune diseases. All the trials in these therapeutic areas are ongoing. And today, I'll highlight a few of the recent updates.

On Slide 16, are the data shared at AACR from our Phase II study in adjuvant melanoma with a combination of our individualized neoantigen therapy plus KEYTRUDA versus KEYTRUDA alone. The Kaplan-Meier curve for relapse-free survival solution here. Overall, there was a 44% reduction in the rate of relapse or death with a combination of INT and KEYTRUDA compared to KEYTRUDA alone. We are encouraged by the continued separation of the 2 curves with a follow-up at 18 months. Note that there are very few participants beyond the 140 week cutoff at the right of this slide, less than 10 participants in total. Thus, as the data continues to mature, with additional follow-up time, we remain cautiously optimistic that this picture will get even better.

Now on Slide 17, I want to briefly highlight some of the additional data that was shared at AACR. The subgroup analysis confirm the strength of the treatment effect across 2 important markers that are known to predict responses to KEYTRUDA. Again, on this slide, we're looking at the relapse-free survival.

On the left side, the results are stratified by high tumor mutational burden in red and low tumor mutational burden in blue. In each case, the solid lines are for the INT combination and the dash line is for KEYTRUDA monotherapy control. If you start by looking and comparing the control arms for KEYTRUDA, you will note that the TMB high participants, the red dash line, have a higher relapse-free survival than the TMB low participants in the blue dash line. This is expected because of what we know about KEYTRUDA, and shows that the controls are performing as we expect.

Now moving to the INT combination arms, the solid lines and comparing them against the dotted lines of the same color, you can clearly see that the INT combination led to higher relapse-free survival for both TMB high and TMB low patients. This highlights the robustness of the response for INT. It's also quite exciting to note that the improved response rate seen in the blue TMB low population, which historically does not respond well -- as well to KEYTRUDA.

On the right, you'll see the result as stratified by PD-L1 status. Now as with the TMB analysis, PD-L1 is known to predict response rates to immunotherapy. As you can see by the dashed lines for KEYTRUDA monotherapy control groups, the relapse-free survival curves look better for PD-L1 positive tumors, these are the red dash lines, and worse for patients unfortunate enough have PD-L1 negative tumors, the blue dashed lines. This isn't surprising as KEYTRUDA monotherapy acts by blocking the PD-1, PD-L1 access.

As with TMB on the left, the solid lines on the RFS curves for the combination show the combination of INT, red denotes PD-L1 positive and blue denotes PD-L1 negative. In both cases, there is an increase in the rate of relapse-free survival with the combination treatment. It is encouraging to

note again that the response rates are significantly improved for the PD-L1 negative patients. Indeed, the hazard ratio in this subgroup analysis is 0.162.

Now pulling back, these data highlights that the observed improvement in relapse-free survival seen in the initial analysis of our Phase II study looks broad-based across subgroups with an indication of a potentially important benefit even in patients who have higher risk of progression, whether due to PD-L1 status or tumor mutational burden compared to KEYTRUDA monotherapy alone.

Now these positive data are just the beginning for this ongoing study. We'll be sharing additional data from the Phase II study at ASCO, including distant metastasis-free survival which was a secondary endpoint in the primary analysis just conducted, and the same data cuts that I just shared. We'll also be sharing important additional biomarker data. In addition, to this protocol calls for subsequent analysis at 51 events, which is when we will also be updating the Kaplan-Meier curves for relapse-free survival with longer follow-up time across the full population, and we eagerly await those updates.

INT has received breakthrough therapy in the United States and PRIME designation in Europe, which will facilitate frequent dialogue with regulators, as we work to quickly advance this treatment for patients. As Stephane mentioned earlier, we plan to initiate our Phase III study in adjuvant melanoma in 2023 and rapidly expand to additional tumor types, including non-small cell lung cancer. We're working closely with our partner, Merck, to explore additional opportunities within KEYTRUDA approved indications and beyond that label. And finally, a quick update on our propionic acidemia program.

Our Phase I/II study is ongoing and currently enrolling patients in the 0.9 milligrams per kilogram cohort. We have identified a dose for expansion and have moved into that expansion arm in the study. I'm pleased to announce just yesterday that a clinical update through the earlier -- time point earlier this year, including an update on safety and the rate of major metabolic decompensation from the higher dose cohorts and including longer-term follow-up from the lower dose cohorts will now be presented at the American Society of Gene and Cell Therapy Meeting on May 18. The abstract for that presentation is now available and can be found in the link on this slide. We look forward to sharing a lot more about the progress of this medicine and our other rare disease programs in the months ahead.

With that, I'll turn the call over to Arpa.

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

Thank you, Stephen, and good day to everyone. I will first start with a review of sales in the quarter. On Slide 22, we summarized the composition of our sales in the first quarter. As you'll see on the chart, our sales to Europe were $0.6 billion and sales to the rest of the world were $1.3 billion. Approximately $1.8 billion of sales from previously announced APAs were delivered in the first quarter of 2023, representing the vast majority of the $2 billion expected in the first half of 2023.

As a reminder, U.S. sales for COVID vaccines are expected to begin in the second half of 2023, with updated strain-matched vaccine. Now as we turn to Slide 23, looking at the 2023 COVID deliveries, Today, we are reiterating a minimum of approximately $5 billion in COVID vaccine deliveries from current advanced purchase agreements. And we continue to expect additional orders from key markets. Of the $5 billion in 2023 deliveries from previously announced APAs, $2 billion, as I mentioned earlier, are expected to be delivered in the first half of 2023. We have already delivered $1.8 billion of that $2 billion in the first quarter with substantial fulfillment to Japan and the European Union. We expect to deliver the remaining approximately $3 billion in previously announced APAs in the second half of this year. Additionally, we expect new sales in the U.S., Japan, European Union, Asia and Latin America. I'm happy to announce that the commercial team has signed a contract with the Australian Government for 2023.

Our discussion with commercial buyers in the U.S. are positive, and I will elaborate on that shortly. In our discussions with commercial customers in the U.S. It is clear that our customers are aware that COVID is still a substantial health burden. Throughout 2022, COVID continued to be a leading cause of hospitalizations. Data available through September 2022, list COVID as the third leading cost of death in the U.S. only after heart disease and cancer, as shown in the first chart on the left. The chart on the right-hand side of the slide shows the most recent data available for U.S. hospitalizations for COVID, flu and RSV. As you'll see, with current season hospitalizations of over 600,000 per COVID, the hospitalization rate for

COVID is almost triple that of flu as well as more than triple that of RSV. There continues to be a clear need to protect against severe COVID infections and our customers recognize that need.

For fall of 2023, we expect the U.S. market volume to be approximately 100 million doses. As we highlighted earlier in the year, the successful transition of our U.S. COVID business from a government driven to a commercial-driven model is critical. We have made great progress on this front, executing on our action plan to rapidly develop this commercial market. Importantly, the commercial team is in active discussions with customers throughout the U.S. We are contracting with national and regional pharmacies, integrated delivery networks, government health providers, including the VA, the CDC and the Department of Defense, for purchasing, organizations and other providers.

In addition, our established national distribution infrastructure and our Moderna Direct e-commerce site is fully operational. Our global supply chain is in place to handle all U.S. customer needs including prefilled syringes and single-dose vials at the time of launch. I'm excited to share some of the launch preparation activities for the updated COVID-19 vaccine for fall vaccination campaigns. We believe these activities will drive consumers to get vaccinated.

First, we are taking an omnichannel approach via tailored digital messaging to healthcare providers. This multifaceted approach will allow us to drive broad awareness and continue to emphasize the ongoing need for COVID production. Later this year, we will be disseminating customized content to drive physician demand across immunizing physicians, institutional decision-makers, as well as influencers.

We are also partnering with our customer base across the different commercial segments to assist with their fall immunization programs. We believe there's an opportunity to continue to provide education, both to staff as well as to patients. And we believe there is an opportunity to harmonize and simplify the vaccination process for patients who are going in to skip their flu vaccine.

Consumer promotion will be focused primarily in the fall of this year, driving patients to seek Moderna's COVID vaccine through significant DTC efforts. As I mentioned earlier, we are looking to simplify the experience for our consumers who are already going in together seasonal influenza vaccine this fall. We are energized for this fall season.

Moving on to Slide 27. I will update you on our second near-term commercial opportunity, which is RSV. We are excited for the expected 2024 launch of our RSV vaccine and the commercial team is undertaking a number of activities to ensure that we develop what we hope will be a large share of that market as quickly as possible. We are already raising awareness of the health and economic burden of RSV by generating and presenting detailed data from our Phase III study at major medical meetings.

Our medical team has shared additional data showing that vaccine efficacy is consistently high across all tested age groups as well as in participants with preexisting comorbidities. The figures on the right-hand side of the slide, detail efficacy data in these important subgroups. As we share these data at medical congresses, we are encouraged by payer and key opinion leader feedback on our data and the application of our mRNA platform to prevent RSV.

We're engaging with payers and NITAG to ensure access upon launch. And the commercial team is active in local markets preparing for a commercial launch in 2024. Specifically, we are building our digital capabilities so that we will be able to efficiently educate customers as soon as the vaccine is approved. And as we invest in prelaunch activities, we have already begun manufacturing components of the vaccine and prefilled syringes. We are excited about the profile of the products we will be launching into these large respiratory markets.

As we discussed at Vaccines Day, the estimated total addressable markets for our 3 key respiratory vaccines are substantial. With COVID, RSV and flu offering potential addressable markets of $15 billion, $6 billion to $8 billion and $6 billion to $9 billion, respectively. We believe we can take a sizable share of this roughly $30 billion respiratory market.

The commercial team is well underway in preparing for RSV and flu launches in 2024. We believe our opportunity in the respiratory market will continue to expand beyond 2024 with our next-gen vaccines and importantly, with future combination vaccines, positioning us to drive share over time.

Now on to Slide 29, I want to share with you how the commercial team is helping identify eligible patient populations in the adjuvant and neoadjuvant settings for various tumor types. Along with our partner, Merck, we have already announced that we will start Phase III trials in Adjuvant melanoma and adjuvant non-small cell lung cancer. There is an annual population of over 130,000 new patients in the U.S. and Europe in these 2 indications.

Patient populations for additional potential adjuvant and neoadjuvant tumor types are listed on the right-hand side. Our commercial teams are working closely with our clinical teams to identify the largest unmet need for addressable tumor types for individualized neoantigen therapy. We are excited to be launching into a space where we have one medicine for one patient in areas of great unmet need in cancer. Given the individualized approach, we are reimagining our commercial model, along with our partner, along with patient care journey, end-to-end.

With that, I will turn it over to Jamey.

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

Thanks, Arpa, and hello, everyone. This morning, I will cover our Q1 financial performance, review the framework for our 2023 financial outlook and provide a quick recap from our recent Vaccines Day presentation. Moving to our first quarter results, starting on Slide 31.

Total product sales decreased 69% year-over-year to $1.8 billion, the decrease in 2023 is consistent with our expectations and mainly driven by lower sales volume compared to the prior year. Cost of sales for the first quarter of 2023 was $792 million, in addition to our unit-driven manufacturing costs, this includes royalties of $86 million and the following charges: $148 million for inventory write-downs related to excess and obsolete COVID-19 products, unutilized manufacturing capacity of $135 million and losses on firm purchase commitments and related cancellation fees of $95 million. These charges, other than royalties, were driven by costs associated with surplus production capacity and an overall lower demand forecast primarily from lower-income countries.

Cost of sales as a percent of product sales was 43% compared to 17% in Q1 2022. The increase was driven by the aforementioned charges over lower product sales compared to the prior year and higher manufacturing costs as we switch to smaller dose vials as well as lower product sales to absorb fixed manufacturing costs.

Research and development expenses were $1.1 billion, which increased by 104% versus the prior year. The increase in R&D spend continues to be driven by clinical trial-related expenses particularly with our Phase III studies for RSV, seasonal flu and CMV. The increase in R&D was also attributable to increases in personnel-related costs due to increased headcount and our recently announced collaboration agreements with Life Edit and Generation Bio.

SG&A expenses were $305 million, reflecting an increase of 14% year-over-year. The growth in spending was primarily driven by continued investments in personnel and outside services in support of our marketed products and related commercialization activities as well as our company expansion.

Income tax provision was a net benefit of $384 million for the first quarter, driven by our full year outlook, which includes international provisions, R&D credits and nonrecurring items. Net income was $79 million compared to a net income of $3.7 billion last year. Diluted earnings per share was $0.19 compared to a diluted earnings per share of $8.58 in Q1 2022.

We ended Q1 with cash and investments of $16.4 billion compared to $18.2 billion at the end of the fourth quarter of 2022. The decrease was driven by a reduction of cash deposits as we delivered products against prepayments and our share buyback activity. Cash deposits for future product supply declined from $2.6 billion at the end of 2022 to $1.8 billion by the end of Q1 2023, in line with our expectations.

Now turning to Slide 33. I want to give an update on the progress we have made on our capital allocation priorities. Our top investment priority has been and will continue to be reinvesting in the base business across multiple areas. As mentioned earlier, R&D spending in the first quarter increased 104% year-over-year, and we continue to project R&D investments of approximately $4.5 billion for the full year of 2023.

As discussed at our Vaccines Day presentation, the majority of this investment is for our respiratory vaccine franchise, which we expect to generate significant returns in the relatively near term. We are also investing in our digital capabilities. the commercial build-out of the organization as well as expanding our manufacturing footprint. We plan to significantly accelerate our capital expenditures in 2023 as we expand both our international and U.S. manufacturing footprint.

Our second investment priority is to seek attractive external investments and collaboration opportunities that will enable and complement our platform. As previously announced, we successfully closed our acquisition of OriCiro in the first quarter and the integration of the operations are well underway. Additionally, we entered into 2 collaboration agreements during the quarter with Life Edit and Generation Bio. We are in multiple active discussions regarding additional external collaboration opportunities, and we'll continue to be disciplined in our approach.

After evaluating internal and external investment opportunities, we then assess additional uses of cash. In the first quarter of 2023, we repurchased 3.6 million shares for $526 million. We had $2.3 billion of share repurchase authorization remaining as of March 31, 2023.

Now let's turn to our updated 2023 financial framework on Slide 34. We continue to have advanced purchase agreements for COVID vaccine sales of approximately $5 billion for delivery in 2023. And we are in active negotiations for commercial market and government contracts in the U.S. and additional contracts for Japan, the EU and other key markets. We continue to expect first half sales to be approximately $2 billion.

Due to the seasonal nature of our respiratory business, we expect sales in Q2 of $0.2 billion to $0.3 billion. We continue to expect fiscal year 2023 reported cost of sales to be 35% to 40% of sales which includes 5% royalties. For Q2, we expect cost of sales between $0.5 billion and $0.6 billion. Due to the seasonal nature of our business, we expect our cost of sales in the first half of the year could be above the range of 35% to 40% and then reduce our average through the second half of the year.

For R&D and SG&A, we continue to expect full year expenses to be approximately $6 billion, with approximately $4.5 billion in research and development. We now anticipate a full year tax benefit of $0.3 billion to $0.5 billion, driven by R&D credits, international provisions and nonrecurring items. And finally, we continue to expect capital expenditures of approximately $1 billion.

Before I turn the call back to Stephane, for those who weren't able to attend or haven't seen the webcast from our Vaccines Day presentation, I wanted to quickly recap the financial takeaways. Given the current significant investment in our respiratory franchise, we wanted to lay out the potential return we envision by the year 2027 for this franchise.

Picking up where Arpa ended her earlier remarks, we believe the market size for COVID, RSV and flu will be over $30 billion by 2027, and we expect to capture $8 billion to $15 billion of this marketplace. While our cost of goods sold percentage will remain elevated in the short term as we transition from a pandemic to an endemic environment, we believe this should normalize to a 20% to 25% range by 2027.

We also laid out a $6 billion to $8 billion cumulative R&D investment required over the next 3 years, which will then normalize to a routine maintenance amount of 10% respiratory vaccines revenue by 2027. Finally, we like the characteristics of the respiratory vaccine franchise, given the highly flexible cost base, low capital intensity, durable future revenue and high potential return, which could lead to $4 billion to $9 billion of free cash flow annually with further room for growth.

This concludes my remarks, and I will now turn the call back over to Stephane.

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

Thank you, Jamey, Arpa and Stephen. Let me share some thoughts before we close into Q&A. Not another promising commercial outlook as several development projects come to fruition. In COVID, we are finalizing discussions with customers. And I believe that we'll see significant additional contracts in the U.S., in Japan and around the world for fall of '23.

COVID is not going away and governments are getting ready for vaccination campaign in the fall. I'm pleased that we have begun prelaunch market development and as risk manufacturing for RSV, which we expect to launch in '24. And in oncology, the team is making great progress. We expect

to deliver key milestones on our development pipeline in the remaining 8 months of 2023. We expect regulatory authorities to give us direction on COVID strain with the June VRBPAC meeting, and we expect to launch an updated COVID-19 vaccine for fall of '23.

We plan to file for approval for RSV vaccine and of Phase 303 flu study should be fully enrolled by this summer, and we expect data in Q4. For INT cancer therapy, we expect to make additional Phase II update, launch of our Phase III study in adjuvant melanoma and expand into additional cancer types. And we'll continue to make progress in our revenues portfolio. We present data for PA on May 18.

This is a very exciting time for us at Moderna, and I would like to thank our teams for all their hard work and their commitment to our mission. Our platform is firing on all cylinders. In Infectious Disease vaccine, look at the data and the portfolio of respiratory, latent and now entering a bacterial vaccine. Very excited by where INT is and is going. And rare disease with PA followed closely by MMA and GSD1a.

We'll give some key updates this year. On September 13, we have our annual R&D there. We will present new development pipeline data and on December 7, we'll be hosting our second annual ESG day. We believe that the incredible progress we have made across all of our modality, positions our company for long-term financial success. But the mission of our company was to motivate our entire team to come to work every day is to deliver the greatest possible impact to people for mRNA medicine.

We believe we have a technology to eliminate or greatly reduced human suffering caused by respiratory viruses, latent viruses, bacteria, cancer, regulating disease and a growing list of other diseases. We work to bring a number of our more promising technologies to market in the next several years and have post to COVID to fulfill on our mission.

With this, we'll take questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Gena Wang with Barclays.

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

I have 2 quick questions. The first one is regarding the U.S. commercial opportunity in the second half this year. You are in discussion with both the commercial and government payer, is 110 to 130 still a good benchmark? How is the pricing play out between these 2 groups? When will you start to see clarity on actual contracts and orders? And then my second quick question is regarding your expectation for ASCO update for your PCV program.

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

Great. So I will start with the first 2 questions on commercial and then hand it over to Stephen to discuss ASCO. In terms of pricing across the U.S. market, we do anticipate our list price when we have our updated vaccine to be in the range of 110 to 130. As you're aware, in the commercial market, we will be providing differentiated discounts across different payer types, from government agencies through to commercial players as well.

In terms of the timing of the orders, we are actively in negotiations with U.S. customers. We are very encouraged on 2 fronts. First and foremost, our customers do appreciate and understand the significant health burden that continued success with COVID. And they do want to partner with us to make sure that as many of their patients can get vaccinated to protect themselves from potential hospitalizations and severe diseases.

The other thing we continue to be very encouraged by in our conversations with different customers if they are appreciating and recognizing the full real-world evidence behind (inaudible) and the effectiveness and profile of our vaccine. So we anticipate over the next 4 to 6 weeks, we will begin to see some more clarity around contracting, which will continue through the end of Q2 and early into Q3.

Operator

(Operator Instructions)

Stephen Hoge - *Moderna, Inc. - President*

Gena had a question on ASCO? Okay. Sorry. Gena (inaudible) presenting at ASCO. So it's Stephen. So as I said, there's 2 presentations, 2 sets of data that will be shared. The first will be focused on the distant metastasis-free survival, DMFS. DMFS, as you know, is another surrogate of overall survival and distant metastasis usually, unfortunately, is visceral, and that's obviously a greater concern.

The protocol for the Phase II study included in the first analysis, primary analysis, looking both at RFS and distant metastasis-free survival, DMFS was a secondary endpoint, and we'll be presenting for the first time that data at ASCO. The second data that will be shared in poster form will be some data on biomarkers and additional data on the performance of INT across populations. That is data that will get more into the basic science for those who are interested in it, but we'll look into the mechanism of action of the product as well as further stratification of risk that we believe provides even more confidence that the signal we're seeing in terms of potential benefit for INT in the Phase II study is resilient and really bodes well for the future.

Operator

Our next question comes from Salveen Richter with Goldman Sachs.

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

With regard to the PA data that we're going to see at ASGCT, could you just frame that for us? I think in the past, you've talked about 25% being clinically meaningful as you look at relative risk reduction in major decompensation events here and what the translatability is from that to MMA and GSD1a and OTC your overall rare disease franchise. And then a second question for COGS, how are you thinking about beyond 2023? And in the context of your assumed market share of the respiratory franchise revenue as you look out to 2027 which you noted, how do you think about profitability in the context of this OpEx spend, including kind of your R&D and SG&A outlook?

Stephen Hoge - *Moderna, Inc. - President*

Thank you for the question. So I'll take the rare disease portion of that on PA first. And so as we shared last September, we did a data cutoff from the PA study last September after a couple of dose levels. And we were seeing slightly more than 50% reduction in the rate of metabolic decompensation. These are the severe events that really, we believe, will ultimately be the endpoint that we're measuring for this drug in terms of benefit.

And what we are going to be sharing at ASGCT is the further update to that. And so this will be a March data cutoff. It's about 6 more months and that will also include at least 6 months at the third dose level, 0.5 mpk and some other emerging data at the next dose level. Again, I don't want to get ahead of sharing what that data is. But of course, we will be looking the strength of that benefit, as we go up in dose, we would hope that we would improve from that 50% reduction in the rates of MDEs, approximately 50% reduction in MDEs.

And we'd also want to obviously see that the drug continues to be very well tolerated with no safety concerns in that patient population. We'll also see much more follow-up time in terms of total time on drug across the entire study which will help to build that case moving forward.

Now on the point of relationship to other programs, propionic acidemia, PA is a sister disease to methylmalonic acidemia, MMA. And as we get more and more confident, hopefully, about the dose level in which we're expanding the PA program and the data we're seeing there, we do believe that reads through very directly into the data that we expect to see shortly in MMA. We have started to see some of that data from that Phase II -- Phase I/II study in population.

I'll remind you that MMA is also chronically dosing in patients and escalating through dose levels. And at the right moment, we will obviously want to provide an update on that data as well in terms of MMA, but we do believe that the PAD to reach really positively through that. And generally, I'd say that's true for our liver metabolic rare disease programs, including OTC and the others that you referenced.

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

And Salveen, maybe I'll take the COGS question. So to reiterate, this year is 35% to 40% of sales. And as you mentioned, we'll go to 20% to 25% by 2027. So I'm not sure it's a perfectly straight line, but let me just give you the factors that will improve that over time.

First is volume. So increasing volume over time as we add new products, our overall manufacturing footprint should give us better leverage. I think predictability helps that so this is a highly unknown season this year. It will be the first time we're transitioning to an endemic. So that will become more predictable over time. ASP, I think, will continue to go up as well. What might offset that a little bit is a greater single-dose file or PFS presentation over time, and we've got some of that budgeted for 2023. So overall, we feel confident inverting our inventory levels down and overall decreasing our cost as a percent of sales.

As it pertains to the 2027 P&L and what does that mean for overall company profitability, we haven't issued any guidance on that. I would say to reiterate for those that heard my prepared remarks, the respiratory vaccine business should generate $4 billion to $9 billion, which we laid out on the page there. And then we'll just have to see, to be honest. We've got an exciting pipeline. We have to understand what's happening with INT. We're quite excited by that, rare diseases, latent diseases as well, and we'll do what's best for all of our stakeholders. So if it makes sense to continue to reinvest some of those profits back into the business, we'll do that. And we're just going to have to sit wait and see where the pipeline looks like at that time.

Operator

Our next question comes from Tyler Van Buren with TD Cowen.

Tara A. Bancroft - *TD Cowen, Research Division - VP*

This is Tara on for Tyler. So I know you mentioned a little bit about timing. But specifically, what we're wondering is, once the COVID strain is selected for the fall and winter season next month, how long approximately do you think it will take to finalize the commercial contracts in the U.S. and abroad? And then separately outside of the U.S., does the recent announcement regarding the ongoing negotiation with Pfizer and Europe actually create an opportunity for you guys to perhaps drive a larger contract in Europe than previously anticipated?

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

Thank you for the question. Your first question around timing of contracting in the U.S. While we are waiting for the final variant strain to be selected in the middle of June, we have already initiated contracting conversations based on an FDA-selected variant. So as I mentioned previously, we do anticipate seeing some of these contracts being signed over the next several weeks, leading into the third quarter. So it will be sort of an evolving time line based on the customer.

From an EU perspective, we're encouraged by the news that the EU is in renegotiations with Pfizer. For us, the signals that the EU likely does not want to rely on one sole supplier. And we also are encouraged that the EU does recognize the value of the effectiveness and safety of our COVID-19

vaccine. So we continue to work with them to see how we can help protect the 140 million people or so in the EU, who are at high risk of COVID infection. And as we get updates on EU negotiations, we will be sharing those as well.

Operator

Next question comes from Michael Yee with Jefferies.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Two areas I wanted to ask on PCV or shall I say, INT cancer therapy. Stephen, you've talked and mentioned there in the slides around time as well as breakthrough designation. And I think you mentioned that you do have a discussion with FDA around your recent data. Can you just talk to the scenarios around a potential accelerated approval, the argument that you have to bring this to patients sooner or do we really have to wait years to run the Phase III? Talk a little bit about how you feel about that this year.

And then the second question, I think, is also important with regard to RSV. Obviously, we'd love to see a diversification of revenues. This could be coming next year. How do you see your revenue opportunity in 2024? Is that a payer battle or a couple of competitors out there, where is your advantage? And how do you see yourself with market share and revenues next year?

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Mike, for the question. I'll take the INT one. So Look, I think it's obviously still early in this discussion about what it will take to bring this medicine forward to patients. And even in the Phase II study, while the data is really exciting, it's probably premature to say that it's sufficient for -- at this point for proceeding directly to accelerated approval. But there are conditions we think over the next year -- or couple of years that could lead to that being an appropriate thing for us and regulators to consider.

In the short term, look, the data is still maturing. We still haven't put out the distant metastasis free-survival data. We're going to be doing that at ASCO. We're obviously excited to share that data, and it starts to just build that more complete picture and DMFS because it looks at visceral lesions does start to look towards perhaps some of those more -- the severity of those relapses that are happening.

We have additional biomarker data that's coming through in that ASCO presentation as well. And both of those data sets are dealing with the initial analysis, which was 40 events. But I'll remind you, we have an analysis at 51 events, which we think will be when these curves are substantially more mature. Obviously, we haven't crossed that yet. And when we do trigger that 51 of that analysis, we will update the RFS curves. We'll update the DMFS curves.

We'll obviously look at statistics around that. And it will be a point in time for us to understand, let's say, with more than 2.5, maybe 3.5 years of follow-up in total median follow-ups on that study. What do the overall curves look like? What are the hazard ratios? What do the statistics look around that? And then what more have we learned about the MOA from all of the ongoing biomarker work that we've done. So that richer data set I think, is really what we are waiting for to see.

There's a second piece of this, too, though, which is that. Any consideration of an accelerated approval, whether it's for INT or just more generically, Increasingly, it's going to depend upon whether or not you have initiated the confirmatory studies and that's appropriate. Because we've all seen how initiating substantially enrolling the confirmatory studies actually helps make sure that, that answer comes quickly and that accelerated approval can either be converted to a full approval or be adjusted as a result of those confirmatory results. And we're very attuned to that. And so our primary focus right now, while we're waiting for the data to mature from the Phase II is to make sure that we stand up that Phase III study and enroll it as fast as possible.

I think the conditions under which we might consider in partnership and discussion with regulators pursuing accelerated approval would really be at some point in the future when that Phase III study is well on the path towards being enrolled obviously not read out yet, but well on the path

there being enrolled and where a lot of the other data I had described had matured and continued to show a really compelling pace for the potential benefit here, perhaps even in patient populations they are at higher risk from a stratification perspective as we were sharing in some of the data today. And that those -- that complement the factors would trigger an opportunity to say it's time to bring this medicine to patients in an accelerated way while waiting for the confirmatory read out.

So premature. All of those things still have to happen. So that's why right now our focus is get that Phase III started, get it enrolled and continue to follow this really intriguing story in the randomized Phase II study.

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

And I can take the RSV question. We continue to be very excited about our opportunity to (inaudible) RSV. The profile of our vaccine as we look at the Phase III data for tolerability as well as effectiveness position us at the high end of the competitive landscape. From a safety perspective, to date, we have not seen any neuro adverse events and our serious adverse events were balanced in both arms as well.

What this means for 2024 is as we look at RSV as a seasonal business, we do anticipate that negotiations will be happening every year in the United States. The repairs will have an opportunity to continue to review the data across multiple players, and we will be working actively to position ourselves in the U.S. commercial market.

Operator

Our next question comes from Terence Flynn with Morgan Stanley.

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

Great. I was just wondering on INT, if you can comment at all about the design of the Phase III in lung there. And then just what's driving that confidence to move forward at this point? Can you just remind us of any data you have at this point on that front?

Stephen Hoge - *Moderna, Inc. - President*

Yes. So it's a couple of things. So first, we did look in the Phase I at non-small cell lung cancer, there were patients in that. Those were not adjuvant patients, but nonetheless, do have some data, biomarker data and other clinical histories, again, not from a controlled study in the Phase I. I think the other confidence is the strength of the mechanism of action that we're seeing and the translation across risk strata in the Phase II study that we've already run, really, we think sets up well as you look at adjuvant indications more broadly, and that's where an adjuvant non-small cell lung cancer, even neoadjuvant non-small cell lung cancer makes a lot of sense from a translatability perspective. And so it's a combination of a little bit of data from that Phase I. The breadth and strength of performance we're seeing in the Phase II for melanoma and obviously, what's been learned with PD-1, PD-1/L1 therapy in adjuvant settings more broadly.

Operator

Our next question comes from Jessica Fye with JPMorgan.

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

A couple of follow-ups on some of the questions that have been asked already. First, on the U.S. COVID contracts for the fall should we expect updates as those are finalized in real time or more like a combined sort of status report, for example, with 2Q results early on in the third quarter.

Second, with the shift to an endemic phase for COVID, do you see any opportunity for improved price for COVID vaccines outside the U.S., for example, in Europe? And lastly, on RSV, how soon do you believe RSV needs to be approved for you to participate in contracting for 2024?

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

Thank you. In terms of your first question on providing updates for U.S. commercial contracts, we are not currently committing to real-time updates per contract. But at a minimum, we will be providing updates at our quarterly calls in terms of where we are with U.S. commercial contracts. The second question around ex U.S. pricing, we do not comment on our pricing, but what I can tell you is for the majority of the countries outside the U.S. We are still primarily in a centralized government procurement model. So we have not set endemic or more traditional commercial pricing yet for most of the markets outside of the U.S.

And the last question, I believe, is on RSV contracting. We are targeting a 2024 launch for RSV, we continue to work through the details of the contracting for the U.S. market in particular. But assuming a 2024 for a launch per our current assumptions, we do believe we will be in time for contracting to launch in 2024 in the U.S. market.

Operator

Our next question comes from Ellie Merle with UBS.

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

Maybe if you could just elaborate a little bit on your confidence in the updated formulation targeting the B strains in influenza. And if you can comment on the dose level if this is studying a higher absolute dose. And just maybe just in terms of this compound, but also just broader in terms of the flu platform as you add additional antigens, just your thoughts on reactogenicity here? And then broadly, with the additional (inaudible) of these compounds? And then second, just in RSV, just a bit of housekeeping. I guess, do you still plan to file this quarter.

Stephen Hoge - *Moderna, Inc. - President*

So first on the flu question. So we obviously have the immunogenicity data that already came out of the P302 study that shows that we've met noninferiority or would have been considered with noninferiority for the B strains. Even in the Northern Hemisphere, study that's ongoing. And so I think our confidence of being able to clear that bar is high and supported by that data even before we made the improvements in the B strain update for the current Phase III study.

We obviously have a preclinical data. We have a lot of experience with updating our antigens and vaccines now with COVID and others. And so we'll look forward to that data in P303. But I think we believe we will do even better than we just did in the P302 study with noninferiority, and we hope to see that we'll be achieving something perhaps trending towards superiority. But that's not the goal specifically for the study. In terms of reactogenicity, and dose -- I'll just say that we are not changing the dose for this 1010 P303 study is still 50 micrograms, so it's not a change in dose level.

And in general, as we think about reactogenicity across our respiratory pipeline, we have a large number of candidates and vaccines where we've gone to doses substantially higher than 50 micrograms. Even in the flu study, we did that up to 100 micrograms on data we shared before. And we believe that there are populations for whom that works well. And in fact, there are vaccines like our RSV vaccine where 50 micrograms is extremely well tolerated. We're very pleased by that profile to date.

And so we actually think it's going to be a vaccine by vaccine case. You can't look at the dose and decide. And as we start going into combinations, we will be optimizing the reactogenicity, the tolerability profile of that vaccine against the benefits in terms of high efficacy that we hope to deliver

and often measured by immune responses in those combination studies. So we currently don't believe that there's a limit on that. But in the specific P303 study, we're continuing down a 50 microgram dose level for 1010.

Now on RSV, yes, we are working closely with regulators on filing globally. And that includes all of the markets in which we hope to commercialize that product and launch it next year. And of course, we'll keep you appraised as we move into those regulatory -- that regulatory process in our normal quarterly updates.

Operator

Our next question comes from Luca Issi with RBC.

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

Maybe on INT, I think you've been highlighting the opportunity adjuvant and neoadjuvant settings. However, I wonder if you could comment on what's the plan in the metastatic settings, is there a place for INT to metastatic settings? And maybe related to it, are you planning to update the metastatic, and the next cancer data set that we have seen at 50 2021? Any color there much appreciated.

Stephen Hoge - *Moderna, Inc. - President*

Great. Thank you for this question. So I think we do think that INT can go both earlier and later in terms of its use. And it's a challenging question about which one do we prioritize in the short term. I think there's a huge opportunity we perceive, we believe, in adjuvant. That is where you hear all of our current activities. That's our focus. That's where we're trying to move into pivotal studies, very, very quickly Phase III studies. But if you look to adjuvant, we do have adjuvant experience. You pointed to the head and neck data. We also have from our Phase I somatic melanoma, there's actually some adjuvant -- sorry, the metastatic melanoma. Metastatic non-small cell lung cancer.

And I think those are situations where we think the burden of the tumor, the size of that tumor is a little bit of a barrier to the potential active activity of any immune therapy. In fact, generally, immune therapies have struggled in later-stage disease and where the real power of the technology, its safety tolerability profile, potential benefit probably is upstream. So while we are following closely the metastatic space, and we did see some intriguing signs in the metastatic head and neck study that you referenced.

We are right now waiting for a little more data to decide whether or not we want to go into those metastatic settings in the short term with our partner, Merck, of course. The other area that I referenced is the earlier stage. And so Stage IIIa, Stage II disease. Disease where immune therapies are not traditionally used right now, but we're a well-tolerated approach like INT that we believe does provide a boost of specific T cell responses against the cancer might have a unique benefit. And again, that's a place that we're eager to explore the INT approach with our partner Merck in the very near term.

We don't have at the present as substantial an effort going into those 2 areas, but we could pivot very quickly. So for now, what we're focusing on is the pivotal studies in adjuvant, we're watching very closely the evolution of our data in metastatic, and we're trying to think about how we could move whether biomarker enabled or otherwise into earlier-stage diseases, I'm sure we will find ways to explore all of those areas if there's a potential for benefit for INT and then it's just now a matter of working down the opportunities as fast as we can.

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

Fantastic. And maybe if I can follow-up. When is the earliest that you can have the COVID plus flu combo potential in the market?

Stephen Hoge - *Moderna, Inc. - President*

I'll comment for (inaudible) very quickly, but the combination vaccine -- so the first point is we want to need to get the flu approved. I think in the Vaccines Day, we talked about our expectations, our hope are to have the COVID-flu combo approved and launched in 2025.

Operator

Our next question comes from Geoffrey Meacham with BoA.

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

This is Alex Hammond on for Geoff Meacham. So given the breadth of your clinical pipeline and the potential opportunities for new vaccines, how does Moderna prioritize assets or indications to go after? And once (inaudible) has, let's say, proof of concept for its Lyme disease, what is your clinical strategy in terms of targeting additional bacterial indications? And then just finally, how are you thinking about capital deployment for the INT program?

Stephen Hoge - *Moderna, Inc. - President*

I'll take the first question. I'll take all 3, I think, but I invite my colleagues to come in too. So first on how we think about opportunities. It's a great challenge we have. We're obviously seeing a very high success rate as we transition into patient populations or pivotal studies across our pipeline. And the short version of it is we look for places where we think our technology through its modalities is well validated. And so we have a high, hopefully differentiated probably success in that next indication and where there is a large unmet need in that indication.

If there's a large unmet need medically, there is usually a large unmet need financially in terms of health care systems, and that's ultimately the kind of value we want to deliver into it. So that's how we approach it. That can be infectious diseases. That's how we think about expanding our respiratory franchise. That's how we're thinking about expanding our latent franchises. We established there. And what you're going to be seeing us do in rare diseases, as we are already doing, is that same sort of expansion as we start to see proof of concept in the rare metabolic disease space.

And then, of course, you asked a question about INT and maybe I'll just jump to the third part of your question, which is how do we think about capital allocation in terms of in INT. There are very few things that have a larger burden of disease, social cost of -- financial costs of obviously a lot morbidity and mortality than cancer. And we do believe that INT has the potential to be a transformational treatment in that space. And so we got to figure out how to do is how do we responsibly, but aggressively grow that investment across a range of different places where we believe that INT will work.

Now we have one significant advantage in that exercise, which is we have a partner in Merck, who has a high degree of conviction around this as well as we talked about, and we are co-investing with them. And so from a capital allocation perspective, we start together looking at what are the indications where there is an opportunity, unmet need in oncology with INT.

As I said before, big focus right now is in adjuvant, but of course, we'll be looking at metastatic and earlier stage disease as well. Last question, I think I'll address is the middle one, which is how do we think about lyme POC and what does it unlock in terms of bacteria. I think we're very keen to address lyme because of the unmet need associated with lyme disease, particularly in the northern -- in Europe and the United States.

But it is a very interesting one for us to demonstrate a bacterial -- antibacterial vaccination. We already have a substantial discovery pipeline looking at other bacteria that if we can demonstrate proof-of-concept in lyme that we will bring forward very quickly. I won't provide updates on those specific targets as that is still preclinical research. But you rest assured, our approach in bacteria will look like our approach in respiratory or latent or INT or rare diseases, which is as we see proof of concept. We will double down quickly with other programs that we think have high probability of success.

Operator

Our next question comes from Simon Baker with Redburn. Simon, your line is open. You can ask your question.

Did you want me to remove Simon from the queue?

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

Yes, you can go to the next question. It will be our last question. Thank you.

Operator

Our last question comes from Hartaj Singh with Oppenheimer.

Eka Gigauri - *Oppenheimer & Co. Inc., Research Division - Research Analyst*

This is Eka on for Hartaj today. So in the slides, you have provided the estimated 2027 respiratory product sales range with the high end being almost double or below. I'm curious if you can talk about to what extent does the stand-alone versus combination share of respiratory vaccines affect this revenue range, and we're just trying to understand the sense -- the degree of like market cannibalization by the combo vaccines? And then secondly, a question on the pediatric RSV program. So the burden of disease for children and caused by RSV is immensely high. Can you talk about your progress in the context of competition in the pediatric RSV program and potential time lines for development.

Arpa Garay - *Moderna, Inc. - Chief Commercial Officer*

Sure. Thank you. I'll start with the first question around the respiratory opportunity. We are hearing significant enthusiasm from both consumers as well as our customer base combination vaccines. We believe that it will enhance compliance and adherence to address the broad respiratory burden of disease by putting these 2, potentially 3 vaccines into 1. So as we think about the commercial opportunity, we do think combinations will be the majority of the opportunity as we look forward in the 2027 and with that, we do anticipate cannibalization of the monotherapy.

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

Just add efficacy, too. So as we continue to improve our products over time, particularly in flu and COVID, I think the better the strain matches better the efficacy, I think, will also advantage us in the future.

Stephen Hoge - *Moderna, Inc. - President*

And pediatric RSV question. So we've actually been working in pediatric RSV as long as we've been in RSV. And so we have ongoing clinical trials including monotherapy and combination respiratory vaccines across a couple of different diseases that impact that population. We completely agree. It is a huge unmet need and area. In terms of guiding forward what timing will look like, we're conducting clinical research.

We'll provide the updates on the data as we see it. We've already actually shared some of the early data from our pediatric programs. There will be both seropositive. So kids who have previously been RSV, there is some benefit there. People -- those children do get reinfected. And that will look more like a boosting set of studies. And then there will be seronegative children. Those are the places where there might be the highest unmet need, those who have not yet had their first instance of RSV, so very young children onto the age of 1. What you'll probably see us do over time is bifurcate those development programs because it end up being very different take -- target populations. And more likely than not the seropositive will move faster and the seronegative will move slower as is normally the case with pediatric development.

Operator

Ladies and gentlemen, this does conclude our Q&A session. I'd like to turn the call back over to Stephane Bancel for any closing remarks.

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

Well, thank you, everybody, for joining us today and for your questions. The next month is going to be exciting. PA data, May 18 and new INT data at ASCO in Oregon. Have a great day. Bye.

Operator

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