Q1 2021 Earnings Call

Company Participants

- Albert Bourla, Chairman and Chief Executive Officer
- Chuck Triano, Senior Vice President, Investor Relations
- Frank D'Amelio, Chief Financial Officer, Executive Vice President, Global Supply
- Mikael Dolsten, Chief Scientific Officer and President, Worldwide Research, Development and Medical

Other Participants

- Geoffrey Porges, Analyst
- Louise Chen, Analyst
- Navin Jacob, Analyst
- Steve Scala, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst
- Umer Raffat, Analyst
- Vamil Divan, Analyst

Presentation

Operator

Good day, everyone and welcome to Pfizer's First Quarter 2021 Earnings Conference Call. Today's call is being recorded.

At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

Chuck Triano {BIO 3844941 <GO>}

Thank you, operator. Good morning and thanks for joining us today to review Pfizer's first quarter 2021 results and financial guidance update, as well as other relevant business topics. I'm joined today as usual by our Chairman and CEO, Dr. Albert Bourla; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development in Medical; Angela Hwang, Group President, Pfizer Biopharmaceuticals Group; John Young, our Chief Business Officer; and Doug Lankler, General Counsel. The slides and the accompanying remarks that will be presented on this call were posted to our website earlier this morning and are available at pfizer.com/investors.

You will see here on slide three our disclaimer regarding forward-looking statements we will make during this call regarding among other topics, our anticipated future operating and financial performance, business plans and prospects and expectations for our product pipeline and in-line products, which are subject to risks and uncertainties, as well as the use of non-GAAP financial information. Additional information regarding forward-looking statements and our non-GAAP financial measures is available in our earnings release, including under the Disclosure Notice section and under Risk Factors in our SEC Forms 10-K and 10-Q. The forward-looking statements on this call speak only as of the original date of this call, and we undertake no obligation to update or revise any of the statements. Albert and Frank will now make prepared remarks, and then to a question-and-answer session.

With that, I'll now turn the call over to Albert Bourla. Albert?

Albert Bourla {BIO 18495385 <GO>}

Thank you, Chuck and hello, everyone. I couldn't be prouder of the way Pfizer has started 2021. During the first quarter, we delivered strong financial results. Even excluding the revenue provided from our COVID-19 vaccine, our revenues grew 8% operationally, 10% reportedly. And this 8% growth includes a negative 5% impact from price. We continued to accelerate production and shipments to our COVID-19 vaccine, in many cases exceeding our contractual obligations for delivery timelines. And we achieved several important clinical, regulatory and commercial milestones.

Let me start with commentary on some of our biggest growth drivers in this quarter. The Pfizer BioNTech COVID-19 vaccine contributed $3.5 billion in global revenues during the first quarter. As of May 3, 2021, Pfizer, along with its partner BioNTech, has shipped approximately 430 million doses of the vaccine to 91 countries and territories around the world. I will share some thoughts on the sustainability of this revenue stream later in my remarks.

Eliquis has continued to deliver a strong performance, with revenues up 25% operationally to $1.6 billion in the first quarter. In the US, Eliquis sales growth was driven mainly by strong volume growth. Vyndaqel and Vyndamax generated revenues of $453 million, representing operational growth of 88%.

Our disease education efforts in the US continued to support a diagnosis, increasing the estimated diagnosis rate to almost 24% at quarter end, up from 21% at the end of 2020. At the end of the quarter, more than 23,500 patients have been diagnosed, more than 17,000 patients have received a prescription and more than 10,500 patients have received the drug, including patients who receive the drug at no cost through our patient assistance programs. While there are still regional differences in cardiology activity and elective diagnostic procedures due to COVID-19 guidelines, on a national basis, diagnosis rates in the US have now recovered and exceed pre-COVID levels as compared with the first quarter of 2020. We also have seen strong growth from Japan and from developed Europe, which is the largest contributor to our revenues outside the US.

Xeljanz also performed well, with global revenues up 18% operationally to $538 million. The growth was primarily driven by 16% growth in the US and 14% operational growth in international developed markets. The underlying prescription demand in the US grew 9% compared with the first quarter of 2020, outpacing the advanced therapy market by 3 percentage points. We have invested in formulary access in the US, which has played a vital role in enabling this volume growth.

In the US, Ibrance revenues declined 7% compared with the year-ago quarter. Total prescription volume is relatively stable, and we continue to be the leading product in the CDK class by a wide margin with an 84% of total patient share in first-line use. However, we saw increased enrollment this quarter in our Patient Assistance Program, which provides Ibrance free of charge to certain low-income patients. We believe this increase is due to COVID-19-related economic hardships that are affecting particularly the demographics of the Ibrance patient population, and we do expect this to normalize over time as the economic impact from the pandemic subsides. As of mid-April, we had contracted for approximately 1.6 billion doses of our COVID-19 vaccine expected to be delivered in 2021. As a result, based on the contracts signed through mid-April, we are increasing our revenue guidance and now expect revenues of approximately $26 billion from the vaccine in 2021.

We also are in ongoing discussions with multiple countries around the world about their needs, and we expect these discussions to lead to additional supply agreements. Based on what we have seen, we believe that a durable demand for our COVID-19 vaccine, similar to that of the flu vaccines, is a likely outcome. We want to be a long-term partner to health authorities around the world in their ongoing efforts to combat COVID-19, including their planning for an ongoing pandemic vaccination approach that is fit-for-purpose to local requirements. To that end, together with our partner, BioNTech, we expect to have the capacity to manufacture at least 3 billion doses in 2022.

We are in discussions with a number of countries around the world for multi-year contracts for the potential supply of COVID-19 vaccine doses during '22 and beyond. In fact, we recently signed an agreement with the U.K. to supply 60 million additional doses in 2021, and with Israel to supply millions of doses in 2022, enough for the government to boost every eligible citizen, subject to local guidelines, with the option to purchase millions of additional doses for additional boosters. We also have reached an agreement with Canada to supply up to 125 million doses in '22 and '23, with options to supply up to 60 million additional doses in 2024.

It is our hope that the Pfizer-BioNTech vaccine will continue to have a global impact by helping to get the devastating pandemic under control and helping economies around the world not only open, but stay open, creating a scenario in which Pfizer can continue to be both a leader and a beneficiary. To realize this goal, we are continuing to lead with strong science, not only to maximize the impact of our COVID-19 vaccine in preventing disease, but also with the work we are doing to develop two potential novel protease inhibitors, one administered intravenously and one administered orally.

As you can see on the accompanying slide, we have many clinical studies ongoing and expect to have multiple readouts and submissions throughout the remainder of the year.

Let me touch on a few. First, while we are currently distributing our vaccine in the US under an Emergency Use Authorization, we expect to submit this month a Biologics License Application to the US Food and Drug Administration seeking full approval for our COVID-19 vaccine for individuals 16 years of age and older.

Second, we are evaluating the safety and immunogenicity of a third dose of the existing formulation of our COVID-19 vaccine to understand the effect of a booster on immunity against the SARS-CoV-2 variants in circulation. Additionally, we have started an evaluation of an updated, prototype variant version of our vaccine that encodes the spike protein of the lineage B.1.351 SARS-CoV-2 variant, which includes the mutation E484K, first identified in South Africa. This study is designed to establish a regulatory pathway to update the current vaccine to address any future variant of potential concern in approximately 100 days, if needed. We expect to have immunogenicity data for both studies in early July.

Third, we are continuing our efforts to evaluate the Pfizer-BioNTech COVID-19 vaccine in additional populations. We expect to hear back shortly from the FDA on our application for expanded Emergency Use Authorization for our COVID-19 vaccine to include individuals 12 to 15 years of age. The Pfizer-BioNTech pediatric study evaluating the safety and efficacy of our COVID-19 vaccine in children six months to 11 years of age is ongoing. We expect to have definitive readouts and submit for an EUA for two cohorts, including children two to five years of age and five to 11 years of age, in September. The readout and submission for the cohort of children six months to two years old are expected in the fourth quarter. We also expect to have Phase 2 safety data from our ongoing study in pregnant women by late July, early August.

Fourth, we are making progress with improving the stability of our COVID-19 vaccine. On Friday, we submitted new stability data to the FDA, and we believe we could soon receive an update to the EUA Prescribing Information allowing the vaccine to be stored at standard refrigerator temperatures of 2 to 8 degree Celsius for up to four weeks. We also are working on a ready-to-use formulation that, subject to generating supportive stability data and obtaining regulatory approval, could potentially be stored at standard refrigerator temperatures for up to 10 weeks, and up to six months at minus 50 to minus 70. If successful, we expect to have the data to support this formulation in August.

Fifth, as we move closer to a potential approval for our investigational 20-valent pneumococcal conjugate vaccine for adults, which, if approved, may be launched during an ongoing pandemic, we plan to begin this month a study of co-administration of the Pfizer-BioNTech COVID-19 vaccine with the 20-valent pneumococcal conjugate vaccine.

Moving to COVID-19 treatments now, we have early studies ongoing for two protease inhibitors antiviral candidates, one administered intravenously and one orally. We expect to begin our Phase 2/3 study for the intravenously administered compound in May and for the orally administered compound in July. With regard to our oral protease inhibitor, we are planning to evaluate its safety and efficacy through three development pathways. We are studying it compared to a placebo to confirm whether it is efficacious against COVID-19. We are studying it against monoclonal antibodies to assess relative efficacy against current circulating strains. Mutations of spike protein may lead to diminished efficacy of presently available monoclonal antibodies, and our intent is to bring about a

therapy with durable efficacy through a different mechanism of action and conservation of the 3CL protein. Also we are studying it in unvaccinated household contacts, exposed to someone infected with COVID- 19 to evaluate if it prevents close contacts from contracting COVID-19.

It has been well established with flu antiviral drugs that administering them to close contacts of subjects who have flu reduces the chance of them also getting flu by more than 80%. Though SARS CoV-2 is a different virus than flu, we are hopeful the principle will be the same. If we administer the investigational treatment to those who are at risk from close contact, does it prevent them from getting sick. As you can see on our timeline, if things go well, we could potentially apply for approvals before the end of the year.

The intravenously administered protease inhibitor is being studied in in-patient Phase 1b studies in the US, Spain, Belgium and Brazil. We expect to begin a Phase 2/3 study, in which the IV compound will be tested against the current standard of care, this quarter. With the current unmet global medical need for anti-virals, we are constantly assessing how we can accelerate the development of these potential treatments.

Pfizer has emerged as a leader in mRNA development, and we are exploring a wide range of opportunities for the technology. We are making rapid progress with our potential flu mRNA program, and we aim to maintain mRNA leadership with two potential game-changing mRNA approaches to a flu vaccine expected to enter the clinic in the third quarter of 2021.

We will test multiple constructs in Phase 1/2 to facilitate swift selection of an optimal tetravalent flu product dose regimen. We aim to develop initially a tetravalent flu vaccine using the modified mRNA platform. Pending the generation of favorable immune and tolerability Phase 1/2 data, a potential rapid progression to Phase 3 is possible, given our large-scale pharmaceutical science and manufacturing capabilities. We also are exploring the potential to address other infectious diseases that we plan to discuss in the near future.

In addition to prophylactic vaccines for infectious diseases, we believe mRNA has the potential to address a wide range of therapeutic areas, including cancer and genetic disease. As you have seen, today we have increased our 2021 R&D guidance to reflect our plans to increase our mRNA capabilities, build momentum in our targeted areas of interest, and deliver on mRNA's breakthrough potential for the benefit of people worldwide. We can expect to hear more about our plans and potential applications in the coming weeks.

Now let's turn to Pfizer's R&D pipeline, which continues to be one of the great strengths. Our pipeline currently includes 99 potential new therapies or indications. That's 99 potential opportunities to change the lives of patients around the world. I will now provide an update on some of these exciting candidates. In Vaccines, as referenced earlier, the FDA is reviewing the Biologic License Application for our investigational 20-valent pneumococcal conjugate vaccine for adults 18 years of age and older with a PDUFA

date in June of 2021. Among pneumococcal conjugate vaccines on the market or in late stage development, if approved, we believe it could provide the most comprehensive coverage against pneumococcal pneumonia disease in adults.

In Internal Medicine, in December 2020, we entered into a collaboration with Myovant Sciences to commercialize Relugolix combination therapy for uterine fibroids and endometriosis, pending FDA approval, as well as Relugolix for advanced prostate cancer. We are excited about the prospect of soon commercializing this product for its potential indication of uterine fibroids, if approved, and the FDA has a PDUFA date of June 1, 2021. An estimated five million women in the US suffer from symptoms of uterine fibroids, and an estimated three million women are inadequately treated by current therapy and require further treatment. We are also working on our planned FDA submission for the endometriosis indication, which we hope to submit this year. An estimated six million women in the US suffer from symptoms of endometriosis, and an estimated one million women are inadequately treated by current therapy and require further treatment unfortunately.

In Inflammation & Immunology, alopecia areata is an immune disease that causes hair loss and has no approval treatments in the US and Europe. The Phase 2b/3 pivotal clinical trial to evaluate our JAK3/TEC inhibitor ritlecitinib in alopecia areata is expected to read out late in the third quarter of 2021. If approved, ritlecitinib has the potential to transform the lives of certain patients with this condition.

The FDA has extended the priority review period for our New Drug Application for abrocitinib for the treatment of adults and adolescents with moderate to severe atopic dermatitis. The PDUFA date has been extended three months to early third quarter 2021, as the FDA has requested additional information and will require additional time to review these data. We believe in the efficacy and safety profile of abrocitinib, which was demonstrated in Phase 3 clinical trial program of more than 2,800 patients. We look forward to working with the FDA and other regulators around the world over the coming months to potentially help bring this important option to patients.

It is important to note that each JAK inhibitor is unique and potential risks identified in one molecule do not necessarily implicate other molecules. We continue to remain confident in the importance of the JAK inhibitor class for appropriate patients with inflammatory diseases given the role of JAK pathways in inflammatory processes. Patient safety is of utmost importance and we continue to monitor all compounds in our portfolio to identify signals both in development as well as after regulatory approval.

In Oncology, we continue to evaluate talazoparib in three studies in prostate cancer. The first is TALAPRO-1, a Phase 2 study in second line plus patients with DDR mutations, which recently had a positive readout as a monotherapy, providing the key proof of concept to move forward in prostate cancer combinations studies. The second is TALAPRO-2, a Phase 3 study in first line metastatic castration-resistant prostate cancer in an unselected population for which the primary completion date is expected in the second half of 2021. And finally, TALAPRO-3, which is beginning soon and will study talazoparib in combination with enzalutamide in DDR-deficient metastatic castration-sensitive prostate cancer.

In February 2021, we announced that the first participant has been dosed in the registration, enabling Phase 2 MagnetisMM-3 study of elranatamab, an investigational B-cell maturation antigen CD3-targeted bispecific antibody, in patients with relapsed/refractory multiple myeloma. New enrollment in this study has been paused while we provide additional information to the FDA regarding three cases of peripheral neuropathy observed in the ongoing Phase 1 MagnetisMM-1 study. Patients who are deriving clinical benefit from elranatamab may continue treatment.

In Rare Disease, our Phase 3 lead-in study for the gene therapy fidanacogene elaparvovec in hemophilia B has now been fully enrolled with more than 40 patients. We remain on course to complete dosing and expect to conduct a planned interim analysis for a potential data readout in the year in 2021. We also continue to progress our hemophilia A Gene Therapy, girocotocogene fitelparvovec, which was developed in collaboration with Sangamo Therapeutics. We anticipate presenting two-year Phase 1/2 data in the fourth quarter of 2021. Additionally, we are pleased to report that our lead-in study for our Phase 3 AFFINE study is in hemophilia A now fully enrolled, which could lead to a pivotal readout in 2022.

For our gene therapy candidate for Duchenne muscular dystrophy, we now have an approved generic name, fordadistrogene movaparvovec, and we are progressing our Phase 3 trial, CIFFREO. To date, we have opened 15 trial sites in eight countries, Italy, Spain, Israel, the UK, South Korea, Japan, Russia and Canada. In the US, we are actively working with the FDA to address outstanding questions related to our Investigational New Drug Application, including technical aspects of our potency assay matrix, so that we can begin enrolling patients in Phase 3 US study sites. While we have high confidence in our current quality control overall and with the potency assay matrix, which has been accepted in countries outside of the US, the FDA has additional technical requests that we are working to address as quickly as possible. We understand the sense of urgency among many families in the US who were hoping for sites to open soon. While we cannot speculate at this time as to when sites may open in the US, we do not expect a resolution in the first half of 2021. We are working with a sense of urgency and hope to reach alignment with the FDA as soon as possible. In the interim, we will continue to progress our trial globally and enroll patients at other sites, which we believe will allow our program to remain on track to potentially enable approvals around the world, including the US.

Now, I would like to address a key policy issue in which we continue to be actively engaged, affordable access. We expect that Biden Administration will soon announce a human capital component to their infrastructure package that will include health provisions. Pfizer is mobilizing to work with the administration, as well as lawmakers in both political parties, on meaningful solutions for patient access. Specifically, there are three key areas where we would like to see Congress and the administration focus, rebate reform, capping beneficiary cost-sharing in Medicare Part D, and incentivizing the uptake of biosimilars. At the state level, we have focused our efforts on meaningful solutions to directly address patient affordability challenges. This includes legislation to require 100% of negotiated rebates to be passed through to consumers at the pharmacy counter. We have also worked with state policymakers to advance legislation in several states ensuring

that patient assistance provided by manufacturers will count towards the patient's deductible and out of pocket maximums.

Looking ahead, we remain focused on being nimble and investing in our R&D organization, so we can build on the strong improvement in the clinical success rates that have been seen over the past five years and potentially translate that success into strong commercial launches that benefit patients. Excluding any impact from our COVID-19 vaccine, we are on track and continue to expect a revenue CAGR of at least 6%, on a risk-adjusted basis, through the end of 2025, as well as double-digit growth on the bottom line.

We remain very confident in our ability to achieve these growth rates because of the strength of both our current product portfolio and our R&D pipeline. At the same time, we will continue to pursue business development opportunities with the potential to further enhance our long-term growth prospects. Just last week, for example, Pfizer acquired Amplyx Pharmaceuticals, a privately held company dedicated to the development of therapies for debilitating and life-threatening diseases that affect people with compromised immune systems. Amplyx's lead compound is a novel investigational asset under development for the treatment of invasive fungal infections.

Thank you. And now, I will pass the stage to our CFO from Frank D'Amelio.

Frank D'Amelio

Thank you, Albert. Good day, everyone. I know you've seen our release so let me provide a few highlights regarding the financials. Clearly, the COVID-19 vaccine has had a dramatic positive impact on our year-over-year results and Albert has addressed the key points on the COVID-19 vaccine landscape. Looking at the income statement, revenue and adjusted cost of sales were significantly impacted by COVID-19 vaccine sales and the associated 50% gross profit split with BioNTech, which we recognize on the cost of sales line.

Revenue increased 42% operationally in the first quarter of 2021 driven by COVID-19 vaccine sales and solid performance from a number of our other key growth drivers. The adjusted cost of sales increase shown here reduced gross margin by 10 percentage points compared to the first quarter of 2020, which primarily reflects the impact of the COVID-19 vaccine gross profit split, which accounted for approximately 8 percentage points, and to a much smaller extent, product mix.

Looking at the business excluding the COVID-19 vaccine contribution, we saw a continuation of solid revenue growth for the business in the quarter, which nicely supports our projected revenue CAGR of at least 6% through the end of 2025. As a reminder, this growth projection continues to exclude any contribution from the COVID-19 vaccine.

In addition, compared with the prior-year quarter, first quarter 2021 revenues were favorably impacted by approximately $400 million as a result of first-quarter 2021 having three additional selling days in the US and four additional selling days in international

markets. This increase in selling days will be offset in fourth quarter of 2021, resulting in essentially the same number of selling days in full year 2021 as compared to full year 2020. However, the favorable impact on quarter-over-quarter comparisons in first quarter 2021 from selling days was partially offset by the non-reoccurrence of favorable revenue impacts related to COVID-19 in first quarter 2020, including increased demand for certain products of approximately $150 million and additional wholesaler inventories of approximately $100 million. Given these factors, the net favorable impact on first quarter 2021 revenues is approximately $150 million or approximately 1.5 percentage points of operational growth, which, in effect, reduces a strong 8% operational growth rate to about 7%.

Reported diluted EPS for the quarter was up 44% compared to the year-ago quarter, while adjusted diluted EPS grew 47% for the quarter. Foreign exchange movements resulted in a 3% positive benefit to revenue and a 1% benefit to adjusted diluted EPS.

Let's move to our revised 2021 guidance. We've again provided total company guidance, which includes the business with the COVID-19 vaccine, and then we've provided some additional sub-ledger detail on our assumptions regarding the projected COVID-19 vaccine contribution so you can also see our projection for the business without the COVID-19 vaccine.

To start, the adjustments we've made to our total company guidance are almost entirely due to the anticipated impact of the COVID-19 vaccine and R&D spending on incremental COVID-19 programs and non-COVID-19 mRNA programs along with a small increase in the revenue outlook for the business excluding the COVID-19 vaccine.

For adjusted cost of sales, the ranges have increased to 38% to 39%, which incorporates the incremental anticipated COVID-19 vaccine revenue which has a significantly higher cost of sales due to the gross margin split with BioNTech as compared to the rest of the business. The projected COVID-19 vaccine revenue, as a percentage of total company revenue, has increased to 36% as compared to 25% in our initial 2021 guidance.

On adjusted SI&A, we have maintained our initial guidance of $11 billion to $12 billion. In addition, we increased our adjusted R&D guidance range to $9.8 billion to $10.3 billion to incorporate anticipated spending on incremental COVID-19 related programs and other mRNA-based projects that are not part of the BioNTech partnership. Working this through with a projected 15% effective tax rate yields an increased adjusted diluted EPS range of $3.55 to $3.65, or 59% growth at the midpoint compared to 2020, including an expected 4% benefit from foreign exchange.

Let me quickly remind you of some assumptions and context on the projected COVID-19 vaccine contribution and our collaboration agreement. As referenced earlier, the Pfizer BioNTech COVID-19 vaccine collaboration construct is a 50/50 gross margin split. Pfizer will book the vast majority of the global collaboration revenue, except for Germany and Turkey where we receive a profit share from BioNTech, and we do not participate in China.

We now expect that we can manufacture up to 2.5 billion doses in 2021 subject to continuous process improvements, expansion at current facilities, and adding new suppliers and contract manufacturers. As of mid-April, we have contracted for approximately 1.6 billion vaccine doses to be delivered in 2021 and still have contracts for potential additional doses under review. Based on the approximately 1.6 billion doses, we are now forecasting approximately $26 billion in COVID-19 vaccine revenue this year. We continue to have three pricing tiers for government contracts depending on the relative wealth of nations.

Our cost of sales for the COVID-19 vaccine revenue continues to include manufacturing and distribution costs, applicable royalty expense as well as a payment to BioNTech representing the 50% gross profit split.

We continue to expect that the adjusted income before tax for the COVID-19 vaccine contribution to be in the high 20s as a percentage of revenue. This margin level also includes the anticipated spending on additional mRNA programs. As I noted earlier, the COVID-19 vaccine is now projected to account for 36% of total revenue for 2021, up from 25% in our initial guidance for the year. Let me add that if we contract for delivery of additional doses during the year, we will provide a guidance update in our subsequent earning releases.

If we remove the projected COVID-19 vaccine contribution from both periods, you will see that we slightly increased the 2021 revenue guidance range to be between $44.6 billion and $46.6 billion, representing approximately 6% operational revenue growth at the midpoint. In terms of adjusted diluted EPS, we continue to project a range of $2.50 to $2.60, which represents approximately 11% operational growth at the midpoint. These growth rates are all consistent with how we've been publicly positioning the business post-the Upjohn separation.

You likely saw our announcement that we have maintained our dividend payment for the second quarter at its current level, despite Viatris announcing their expected dividend payment. For those continuing to own Viatris shares, this effectively represents an increase in the dividend income and our Board felt that the strength of our business supported maintaining our dividend. For the foreseeable future, we expect our Board to continue to support annual dividend increases at approximately this year's level. Obviously, we have no say as to what Viatris does with its future dividend.

In summary, a tremendous start to 2021, the COVID-19 vaccine continues to benefit millions of people around the world and the business is on track for anticipated solid top and bottom line growth. We remain focused on advancing our pipeline, supporting in-market brands and looking to deploy capital responsibly with a focus on initiatives that can solidify our long-term revenue and earnings growth outlook.

With that, I'll turn it back to Chuck.

Chuck Triano {BIO 3844941 <GO>}

Great. Thanks, Frank and Albert, for your prepared remarks. At this point, operator, let's move to our Q&A session, please.

Questions And Answers

Operator

(Operator Instructions) Your first question comes from the line of Louise Chen from Cantor.

Q - Louise Chen {BIO 6990156 <GO>}

Hi. Congratulations on the quarter and thanks for taking my questions here. So first question I had for you, what are your thoughts on the slowing vaccination rates in the US? Do you anticipate things to pick up again? And will we reach that level of herd immunity in the US here? And then second question I had was on a vaccine sales and how you think about it beyond 2021 and 2022, what gives you confidence that there is going to be a tail here? And how does that tail look relative to the $26 billion that you're going to potentially have this year? And then last question I had for you is just on how you're thinking about FDA concerns around JAK safety? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much, Louise. So let me make some comments on the slowing vaccinations maybe a little bit on the '22, '23. Revenues, I will ask Mikael Dolsten to add some comment over there. And then for -- on the JAK, I will ask him to make some comments about the stages. Look, I think the US has done a tremendously good job and they have reached vaccination levels that we didn't think that they will. The truth is that as we are vaccinating more and more people, the people that are reluctant to get the vaccine are reaching the remaining pool. So it's normal to expect that we will see a drop in the vaccination. But I believe that the entering of additional pools like younger people post the expected approval of our 11 to 15 years old vaccination also will provide an additional increase in the vaccination rates. All in all, I think US is doing very good job and the focus of all should be to convince those people that they have still fear about the vaccine that they must do the right thing.

Now, beyond '22 and '23, first of all, we believe, as we said multiple times, that there will be a need for boosters and there is a need likely from now all the way to (technical difficulty) and then believe that the likely annual vaccinations or let's say regular vaccinations will be required. Clearly, this belief is based on the totality of the evidence and not on the study that they have read out right now to convey that this is the case. And the totality of the evidence is having to do with the fact that we still have very high efficacy of 90% -- above 90% in our six months, but it is slower at 91% than 95% that we had in the beginning. So there are some indications that the there is a drop in the efficacy over time.

We now have been -- there need to be studies of neutralizing antibodies, (technical difficulty) that also there is a drop on these antibodies and that affects not only people that they are with the vaccination, but also are naturally infected. We also know that after six months, the increase of -- the infections to people that they had previous infections is

increasing. And we also know that we are right now, our vaccine at least is effective against all the variance that we have seen, but there is a drop neutralizing titers, which means that the main server will maintain good efficacy against the variants. You need to increase the immunogenicity and this is why we're doing the strategy with the boosters. So the totality of the events are pointing out to this and this is the reason why basically all governments of the world are now discussing with us about procurement agreements for '22, '23 and '24.

But I will ask also Mikael Dolsten to make some comments on why we think that the boosters and repeated vaccinations is a likely scenario. And also a comment on the JAK safety? Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you, Albert. I thought your outline in an excellent manner that we have identified a handful of key points related to immunity with induced by convalescent of the infection of vaccine that will over time, as expected, show some decline, antibodies will show some decline as their half-life are limited, of course, protection contains other immune mechanisms. When you put all of this in context, that SARS-CoV2 is globally circulating to extent we have rarely seen or ever seen in our lifetime of a virus. And the inability to control it across the globe we will of course lead to numerous changes in the viral mutation rate. So it just punctuates what Albert said, we need continuously to keep up a very high immune pressure against the virus to stay ahead of the curve and the best way to do that is with regular boosting.

And finally, herd immunity, while we would like to see it establish, what you hear from a lot of public health data and global health data emerging is that it will be really difficult in large continents to establish such a high immunization rate across all ages and to ensure as you immunize one part of the continent that immunity is maintained at another part. So I think we would really need to rely on regular immunization and, of course, other public health measures brought in and hoping that herd immunity across the globe can be established.

Finally, on the JAK safety, already in February '21, FDA made it public about our data in 1133 related to increased risk of serious heart related problem and certain cancer, when compared to another type of medicine, the TNF inhibitors. So these data are clearly not new. FDA, EMA and other agencies work in dialogue with us to finalize the outcome of this review. On the other hand, I think the JAK class has shown to be an important contribution as an oral alternative for many patients and you avoid other issues such as anti-drug antibodies with biologicals. So, we continue to wait for finalization of the outcome of the 1133 trial. We think each JAK inhibitor is unique, and it will be assessed by itself. And we continue to believe that with the proper labeling and given the tremendous experience of Salient since 2012, it will continue to have a potential to be an important medicine.

A - Chuck Triano {BIO 3844941 <GO>}

Right. Thank you. Operator, next question, please.

Operator

Your next question comes from Terence Flynn with Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Great. Thanks for taking the questions and thank you for all the work on the vaccine front. I just had a follow-up on the booster question. Do you think that will be uniform across different groups? Or will there be any differences by baseline characteristics such as age in terms of the timing of a need for a boost? And then would you expect FDA and CDC to issue a recommendation on the need for boosters sometime this year?

And then my second question for Albert or Frank is just would welcome your perspective on the potential impact of tax rate changes in the US. And any thoughts on how that might change your capital allocation strategy and/or views on inversions. Thanks.

A - Albert Bourla {BIO 18495385 <GO>}

Mikael, why don't you take the question for the boosters?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, I think we cannot, of course, predict what CDC and similar agencies will do. But what seems to be the general public dialogue and which, of course, builds on experience with other viral epidemics and this is, of course, a pandemic, is that you would likely start with those that the most susceptible older adults, those with chronic diseases such as cardiovascular, obesity, COPD, asthma, many that are immune impaired, and, of course, that constitute a very large population. While you may start with those, if we are to really maintain control of the virus, it will be very reasonable to assume the importance of also vaccinating younger groups. Although severe COVID is less common in younger groups, some patients may suffer severely from such infections and they are at risk also of acquiring long COVID syndrome, which can cause significant impairment of participation in functional life for young individuals, as well as old. So, in all in all, yes, regular boosts of the entire population is a clear possibility. Priority is to start, of course, with the many vulnerable from age to chronic diseases, which is a large number of the adult population.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Mikael. And Frank, would you like to take the question about the tax?

A - Frank D'Amelio

Sure. Thank you, Albert. So, I think it's premature to comment on what impact the proposed tax rate would have on our (technical difficulty) how we view capital allocation and inversion simply because these kinds of proposals typically go through multiple iterations, multiple discussions, multiple negotiations. Obviously, we're staying very close to this, doing all the analytics that you would expect us to do. But I think what's really important is how we think about tax, taxes and tax policy. 2017 tax reform leveled the playing field for US multinationals against foreign competitors. And that was an enabler from my perspective of much of what we've done with capital deployment, particularly in

the US. We committed to $5 billion of CapEx investment between 2018 and 2022. We committed a few billion of at-risk capital in order to develop the COVID vaccine. The funding of our US qualified pension plan that we did last year to the tune of over $1 billion. All of those from my perspective were enabled by the level-playing field that we now get to compete on against our foreign competitors. And so, what we want from tax reform when all is said and done is we want that level playing field to continue so that we have the ability to compete on a level-playing field. So, that's my answer, Albert.

A - Chuck Triano {BIO 3844941 <GO>}

Thanks, Frank. Next question, please.

Operator

Your next question comes from Geoffrey Porges from SVB Leerink.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you very much for taking my questions. Again congratulations on a remarkable quarter and really tremendous progress. Some quick questions. First on pricing, you mentioned the 5% price headwind. Could you give us a sense of what that looks like for the rest of the year? Is that something that we should be expecting for the full year or is it just a Q1 phenomenon?

And then related to that, Albert, you disclosed your view on the pricing policy and regulatory and legislative update. But is what you described a realistic case or is that a best case?

And then a couple of questions for Mikael. Mikael, I've asked you this before, but given what we're seeing in India and in other geographies, is it your view that COVID is going to be a case of convergent evolution or continuous evolution, i.e. are we seeing new mutations beyond E484K that have additional resistance mechanisms to the first generation of vaccines and antibodies?

And then just lastly, you mentioned mRNA, you have a maternal RSV vaccine. Are you planning to apply mRNA as a more efficient approach to getting neonatal and infant coverage against mRNA? Thanks -- against RSV, sorry.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Geoff. A lot of questions, very important. Now, let me speak a little bit about the policy of the prices and then I will ask Frank to comment little bit on the pricing, and if Angela needs to add something, please feel free. And then on the two other areas, clearly, Mikael will speak about the resistance and the mRNA.

On the pricing reforms, these are our standard positions. But I will try to explain how I feel about the pricing reforms. And I've said it in multiple locations, we don't think that the statute law is good for anyone. I don't think it's good for the industry. I don't think it's

good for the Americans, because there is a problem with the current way of -- the current system. And this is a problem that basically every American is paying for their medicines, and this is unique to medicines, not to other medical interventions, is paying out of the pocket like if they don't have insurance, although they do have insurance. And this is the fundamental thing that needs to change. Because the medicines contribution to the overall healthcare, it is 12%. So by definition, cannot be the big issue. But it is becoming the big issue in the discussion, because everybody has to pay this thing from out of pocket almost unlike other interventions.

So, what a change could look like? And for us, a change could look or take different forms. It could be consistent from different areas, may not be very bad reform, which I think is just one of the sustaining issues that we are having with drug pricing, but it could be that out-of-pocket costs. The fundamental thing it is that there will be a cost of the industry, I'm sure, will be willing to take our fair share, as long as all the savings, all the contributions what we are doing right now from this industry will go into the pockets of the American patients. And this is a fundamental difference with people that are discussing right now, because we are hearing a lot of suggestions, but they want to tax the pharmaceutical companies or tax the insurance companies, but the proceeds will just fall in the black hole of the federal budget, which is not what we want. If our contribution is going to the patients, we are sitting down with all of the parties trying to do a decent price reform in the way that the Americans are experiencing the costs when they go to the pharmacy to collect their medicines.

So, is it realistic or optimistic? I believe it is realistic. I believe that there is room for agreement, both with the two sides of the aisle and with this administration. And we will continue working on finding the solution, but will, I repeat, make medicines affordable for the patients and not throw money to the black hole of the federal budget.

Now, Frank, if you can take the price increase and then Mikael.

A - Frank D'Amelio

Okay. So, you've heard Albert and me talk about pricing and that pricing has been a headwind and we expect it to continue to be a headwind for the foreseeable future. And that's obviously what we saw this quarter with pricing being a negative 5% on a global basis. I should also mention, it was a negative 5% in the US. Now, in terms of our guidance, which is what you asked, Geoffrey, our guidance assumed the pricing decrease to be a negative impact, I'll call it in the range of low to mid-single-digits. So that 5% reduction that we saw this quarter is consistent what we assumed in our annual guidance.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Frank. And by the way, I wanted to add that this minus 5% that it is the reality of the numbers. I'm sure that many Americans have an experience during this quarter, a 5% reduction in their out-of-pocket. Because if the system that works in a way that no matter what you do, on the top their price that they had to pay is derived from very different rooms. Mikael, can you speak a little bit about the resistant mechanism the mRNA or RSV?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you. I'll start with mRNA, as you discussed here, Geoffrey, of course, there is tremendous viral amounts across the globe fueled by the spread in large population areas like India. We do see several different lineages of SARS-CoV-2 establish. They however seem to share the most critical mutations, most of the variants have up to 10 mutations and they can combine from different ways. So far we believe that our b2, the current vaccine is very effective in controlling all known mutations. But, as Albert alluded to, we believe it's very important to keep up very high neutralizing antibody levels in addition to the nice T-cell immunity and that's why a possible outcome of this tremendous spread including India is to have regular boosts.

As the pandemic continue, up to now mutations have been selected mainly because the virus is trying to spread more quickly. The virus will now face vaccinated immunity in maybe '22, '23 increasingly, so we need to be prepared that there could be new unexpected mutations to come and that's why Pfizer is leaving no stone untouched and also have variant vaccines developed and could be on alternative later if that scenario would emerge. But right now, it seems like the current vaccine is very effective against all these variants despite each having up to 10 different mutations.

On the RSV, well, we had very robust titers with our protein based RSV vaccine in maternal vaccination and very good tolerability and antibodies passed efficiently through the cord blood and we are enrolling now well in Phase 3. We also have initiated a Phase 2 challenge study with RSV that will read out mid of the year and that could plausibly lead to progression swiftly into Phase 3. So we are pretty advanced with the protein base, it looks very good. But, of course, we have now mRNA platform that we would like to use for multiple opportunities we expect to put into the clinic two first in humans novel vaccines every year for the next few years. Certainly, RSV could in the future be one alternative, whether it could be a supplement to the protein base in order to add some T-cell immunity, these are things we'll continue to explore and then prioritize among the many exciting opportunities for our mRNA platform.

A - Chuck Triano {BIO 3844941 <GO>}

Great, thank you, Mikael. Next question please.

Operator

Your next question comes from Steve Scala from Cowen.

Q - Steve Scala {BIO 1505201 <GO>}

Oh, thank you so much. I have two questions. Regarding the DMD gene therapy, is the potency assay issue related to concerns around correlation of biomarkers to motor function efficacy or is it simply a technical issue with no bearing on relevance of the endpoints?

And second question is a little bit more broad-based. But in the COVID vaccine, Pfizer has built the world's largest global pharmaceutical franchise in six months. I imagine that it is

creating a substantial stress throughout the organization similar to the disruption of a major acquisition. What metrics do you monitor to ensure that these stresses are not going to show up in one to three years or so as say subpar product performances, clinical trial failures that otherwise would have been successes, and maybe missed M&A that would have otherwise made sense for Pfizer? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much, Steve. Mikael, would you like to take the DMD question? Is it the technical issue what it is?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, so the DMD trial, first of all, and I think Albert mentioned that in his introductory remark, is enrolling in many different countries. And in each of those, we had a matrix of assays that were cleared by the regulatory authorities. The particular discussion with FDA is more of a technical issue on how to do a quantification in one supportive assay, but not really as per our view in any of the main assays. So we continue to work with them and aim to resolve it. I want to point out that to the best of my knowledge, we were first start the DMD Phase 3 now enrolling well outside the US late last year and we are probably by now, we're entering May six months ahead of anyone using gene therapy that is public, it hasn't been disclosed any other having been cleared here yet.

A - Albert Bourla {BIO 18495385 <GO>}

Okay. Thank you, Mikael. And Steve, it's true that in order to achieve what was achieved during the -- with this vaccine, the ingenuity of our people was a key component, but also a lot of personal sacrifice had to be involved. So a lot of the people who worked day and night a lot, a lot of these people worked days and nights to make sure that this happens and that clearly has taken a toll on them. And no matter how proud they feel, because the passion that they have can keep them going forever, I am concerned that we need to find ways that these people were not burned out.

But I need also to emphasize that Pfizer is run in the form of business units since 2016, when I was running the business that basically Angela is running right now and we have organized the whole operations into six business units. And that involve the R&D, the commercial, and the clinical development. So the work for COVID happened in one of the six business units. And happened predominantly in the R&D domain of these clinical units. But at the same time the Oncology business unit and the Rare Disease business unit and the Internal Medicine business unit and all the other business units that were heavy kept working on their normal, let's say, workload, let me put it that way. They helped, of course, also to overcome issues related with the COVID-19, but didn't make their work very easy. But again, they were being able to rise to the occasion, because I believe everybody in Pfizer right now is so strong believer of the culture that patients come first. And this is not about us, it's about them.

So this sense of sacrifice that we see in the vaccines, we have seen it also in the other units. People are very passionate about what they do and they feel very proud. So I'm giving the answer to say that there is a very intense, let's say, disruption that happened in

part of the organization, not in the entire organization, but has been offset by an incredible sense of pride that those people are taking because of what has been achieved. So I can't control them in terms of how hard they are working right now on all the other vaccines, for example.

A - Chuck Triano {BIO 3844941 <GO>}

Great. Thank you, Albert. Next question please.

Operator

Your next question comes from Vamil Divan from Mizuho Securities.

Q - Vamil Divan {BIO 15748296 <GO>}

Great, thank you so much for taking the questions. And like others said, thanks so much for all the efforts around COVID. So a couple of questions that I have. So one, I guess there's obviously some debate around the durability of your vaccine sales and cash flows. But you clearly have a lot more sales and a lot more free cash now to potentially invest and you probably envisioned a couple of years ago because of the vaccine. So I'm just thinking you are obviously investing more behind the COVID vaccine and therapeutics. But can you just talk about your priorities from a capital allocation perspective? Now, I don't think -- you mentioned you don't want to share repurchases, but are there priorities that you could maybe look to whether it's bringing in external assets or maybe doing larger deals given the extra cash that you now will have? And then maybe the second one, I guess, for Albert, and maybe a little bit more of a personal angle here, but I appreciate your comments you made around the COVID crisis in India, recently. I'm just wondering if you can provide some clarity on the status of getting your vaccine to the market there. I think you filed back in February and then there are some questions about maybe doing a trial in India, I think some question around indemnification around side effects. Can you just clarify where things stand there and what might be reasonable in terms of timing to get the vaccine available to the patients there? Thanks.

A - Albert Bourla {BIO 18495385 <GO>}

Yes, thank you very much. In terms of -- let me start with that. In terms of the vaccine in India, we applied months ago as you know. And in -- and we applied exactly the same file that we gave to the entire world, FDA, EMA, Japan everybody in the world. India wanted to do additional studies in order to approve this vaccine over there, which clearly we were not ready to allocate resources doing something like that, whether -- when we were allocating all the resources to do things into the variants, the kids, pregnant women and that can go on, things that we haven't done it before. But the Indian government is really very good in having discussions right now with us about all these issues that we have raised. So we are hopeful but they would change this policy about conducting some local trials. And we will find a path forward so that we can provide the vaccines.

That being said, the key right now today and in the next one or two months, it is that people are dying in hospitals in India. And vaccines will not change that in the next one or two months. I think that would be a reality that we have to live with right now. And what is more important is to make sure that the Indian government has enough medicines to treat

the people that they're going to the hospitals right now. And this is why yesterday we announced that for four of our medicines that they are in their government of protocol, because the authorities have developed a protocol of treating COVID patients, and there are four of our medicines involved in these protocols. We will provide enough of these medicines for every patient in every public hospital in the next 30 days. And as we speak, we are ramping up production of these medicines in Europe, in the US, in Asia, and we are ramping up distribution channels so that we can ship as quickly as possible those medicines to India because the need is immediate.

Now, on the capital allocation, I will ask also Frank to make some comments here, but very few things are changing because of that. Our strategy on capital allocation was not driven with how much capital we had. It was driven with how much opportunity we had. So we never say never to anything, so we maintain the right to -- to see -- to be flexible. But clearly, Frank spoke about it, a growing dividend, it is a part of our investment thesis, so that will be maintained. And also we said that our investment in research, our investment in manufacturing, our investments of our capital are all aiming to improve the longevity, how durable it is our growth in the second part of the decade. So you should expect to see a larger Phase 2, Phase 3 business development deals that will allow us to bring in-house a lot of potential medicines that could become medicines in this timeframe. Frank, anything to add?

A - Frank D'Amelio

Yes, Vamil, you're absolutely right. Obviously, the COVID business is generating incremental free cash flow for us. But from my perspective, not material enough to have any major impact on our capital structure. And to Albert's point, the term I would use is we will stay the course in terms of how we deploy our capital. And then Albert obviously mentioned the key areas where we would deploy it, right, the dividend, investing in the business and you saw that with the R&D guidance increase this quarter and then M&A, and M&A really focused on growth the second half of the decade.

A - Chuck Triano {BIO 3844941 <GO>}

All right. Thanks. Thanks for those insights, both. Let's move to our next question, please.

Operator

Your next question comes from Umer Raffat from Evercore ISI.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my question. Frank, there was a comment you made back in March, which got a lot of attention. And I thought perhaps you could elaborate a bit more on how you're thinking about the durability of COVID revenues and perhaps lay out sort of the volume and price element of it beyond 2022? And if you could also perhaps speak to the pricing seen in your Canadian contracts, whether it's consistent in 2023, '24 versus where it was in the '21 contract.

And then I had a quick R&D one as well, if I may. I know there is these additional FDA technical requests on the gene therapy assay for DMD. I recall you guys were using ITR in Phase 1 and then you switched to a transgene assay in Phase 3, because there was a little more low variability. Is FDA now thinking the variability is higher than they want in the transgene assay as well? I'm just trying understand what the word quote-unquote "matrix" means. Is it still just the transgene assay with different methods or are there multiple assays at play now? Thank you so much.

A - Albert Bourla {BIO 18495385 <GO>}

Frank?

A - Frank D'Amelio

Thank you, Albert. So on pricing, Umer, I really want to not going into detail on pricing other than obviously there are certain contracts where we disclosed with the prices. In terms of the way I think about this, what we're really focused on now is getting doses to the patients that need doses around the world that makes -- that getting people vaccinated, that's been our focus, that's we're acutely focused on that. You heard in our prepared remarks we said we can make approximately 2.5 billion doses this year. We can take that up to 3 billion doses next year and that's what we're really focused on, right, getting those made, getting them delivered and getting vaccines at the patient's arm. So that's the focus.

On the Canada contract, we didn't discuss pricing on that contract. What we did say it was up to 125 million doses in 2022 and 2023 with an option for more doses in 2024. And then in terms of the durability of the franchise, I'm going to try to not to repeat what Albert said, but I thought Albert went into a lot of detail on why we believe the COVID revenue franchise has a significant durability and why we think we see that is something that's going to take place for the foreseeable future. And Albert went through a lot of the details that we believe that is.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Frank. Mikael, about the technical question?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. The core assays that you alluded to related to AAV and transgene effectiveness are all without any really comment by FDA. So they were all fine. This is what I call the supportive assays, an adjunct assay that was more related to co-localization of the DMD protein and discussions on various technologies how to measure that. And as I said, in Europe, as this was an adjunct assay in other countries, we have cleared and then enrolled efficiently and progressing towards the next step of the trial very well. So it's a very technical issue how to do a detection, but not related to the core potency assays. And obviously we're working to resolve it, but what I understand, currently there is no other potential gene therapy in US that have cleared yet to Phase 3 and we obviously would like to be first, not just ex-US where we have been going for six months, but also in US and work diligently to resolve these very technical questions.

A - Chuck Triano {BIO 3844941 <GO>}

All right. Thank you, Mikael. Next question, please.

Operator

Your next question comes from Tim Anderson from Wolfe Research.

Q - Tim Anderson {BIO 3271630 <GO>}

Hi. Couple of questions please. On mRNA and your flu vaccine plans, how would a trial be constructed and really what's the goal? Are you looking to show superiority on efficacy or just hoping to achieve parity with existing vaccines? And you talk about yours being quadrivalent, so presumably, if there is a comparator that would be something like Sanofi's Flublok? Also what would be the likely development timeline? I'm guessing it's not as fast as a COVID vaccine that it would take something longer maybe a couple of years. And then a separate question, on your five-year guidance, just what -- just to make sure I understand your earlier comments on pricing, what does your five-year guidance assume about drug pricing, especially in the context of there possibly being European drug pricing austerity measures due to COVID?

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Tim. And Mikael, do you want to take the question about the flu?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, with the flu vaccine, given the strong immune response we have seen for our mRNA platform. We certainly hope to be able to show substantial differentiation versus current flu vaccine. This is, of course, the aspiration we have. Technically, there will be two components. One is to look at immune response on antibodies that have certain standards reported related to increase in titer and we will be able to compare to the current protein-based flu vaccines. And then we are also planning to run a vaccine efficacy study, where we think it's not just what we hope to be a very potent antibody response, but also the T-cell response. So I would certainly aspire too that we would have a vaccine that needs to be substantially meaningful, better than the current vaccine, based on the platform by itself, but also based on that we are able to pass to align the platform with the sequence of the emerging flu strains, while, as you may know many years, the protein base are misaligned and that's why you get very modest vaccine efficacy on maybe just 50% and similar for immune responses. So given that we saw 95% efficacy against COVID, we think there is a large margin for us to improve in the current flu vaccine.

On the timing, Albert said, we are moving to start human trials in Q3. And we will obviously, early on, generate data on the immunogenicity and if that continue to go as well as our aspiration, we think we can move very fast with this vaccine and also utilizing the type of approach, where you establish a large number of the sites in the regions to study in order to enroll very fast. And we will look at various ways to register this vaccine and also how that could coincide with the recommendation by ACIP. So while we don't

give at this early time an exact date, but anticipate that we will move very fast, may not be as fast as the pandemic development, but much faster than a traditional flu development.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Michael. And then, Frank, I know you did answer the pricing, but do you want to say a little bit more about it?

A - Frank D'Amelio

Sure, Albert. And this was more about the five-year CAGR through 2025.

A - Albert Bourla {BIO 18495385 <GO>}

Correct.

A - Frank D'Amelio

So I think, Tim, the way I think about it is we really look at pricing by geographic region. And we consider -- we're going to continue to believe it's going to be a headwind by geographic region what would be examples of that. The US would be one, emerging markets would be one, developed Europe would be one, just as an example. They all range in, I'll call it, negative pricing increases in the ranges low-single-digits to high-single-digits. And obviously, we blend that all together into an overall global rate. And that's what we've assumed in our category assumptions through 2025.

A - Chuck Triano {BIO 3844941 <GO>}

Great. Thanks, Frank. Operator, we can take one more question and then we'll have some closing remarks from Albert following that.

Operator

Your final question comes from the line of Navin Jacob from UBS.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi. Thanks so much for fitting me in here. Just a couple on the mRNA vaccines that you're pushing forward. You had been working with BioNTech for your flu vaccine. I just want to confirm that you're using the Pfizer mRNA technology for the flu vaccine that you're moving forward with. And I'm curious as to why you going with that approach beyond just the economic benefit of using your own tech versus something that you're collaborating with on. Is there something different about your mRNA technology, whether it's in the non-COVID portions of the vaccine or the LNP?

And then secondly again on the flu vaccine, what is your ability to co-formulate it with the COVID vaccine? Wondering why you're moving forward at the co-formulated Prevnar 20 plus 162b2 and not looking for the flu vaccine co-formulation? Thanks for your thoughts. Appreciate the time.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much. As regards the flu vaccine, we had a collaboration with BioNTech that goes back to 2018. At the time, we had announced also publicly some of the terms of this agreement and the developments are based on the work what has been done so far by both companies on the flu. As regards to the question of co-formulated, we didn't announce a co-formulation with Prevnar right now. We announced co-administration with Prevnar. Clearly, we are looking at options to co-formulate the BioNTech-Pfizer mRNA vaccine against COVID with other, let's say, vaccines. But this is not what we spoke about it today and we haven't made final decisions on co-formulations.

And I think, Chuck, we do not have time for another question, right?

A - Chuck Triano {BIO 3844941 <GO>}

That's right, Albert. (multiple speakers) closing remarks.

A - Albert Bourla {BIO 18495385 <GO>}

Okay. Just I wanted to thank everyone for joining us today and for your continued engagement with Pfizer. I think the pandemic has been the ultimate test for Pfizer's and in truth, the entire pharmaceutical industry's capabilities and credibility. And in my view, we have thus far passed with flying colors. The success of our covenants in vaccine has led to an important question, if we could do this for COVID-19, why not for other diseases. There are so many people suffering from other serious diseases and their needs aren't less urgent. We now see an opportunity to take the lessons learned and new ways of thinking and apply them across our entire portfolio. The speed with which we interact with regulators as well as the continued acceleration of digital solutions, such as artificial intelligence, electronic diaries, advanced analytics and electronic health records are just some of the things we plan to bring to all of our clinical trials so we can continue to move at the speed of science.

And now before we end the call, I want to take a moment to extend my thanks and very best wishes to our colleague and good friend of mine, Chuck Triano, who will be retiring at the end of September. Chuck has been interacting with the global investment community for nearly 35 years, including the past 13 years here at Pfizer. And I think all of you would agree that during the time, he has elevated Pfizer's Investor Relationship -- Relations function to a best-in-class. That's because he brought us clarity, integrity, and transparency in the way to communicate. And it is because he has a passion for our company and our industry what makes him an outstanding champion for both. The good news is that he will be around for at least one more earnings cycle and perhaps another as he has agreed to stay on us advisor during this transition. Chuck, thank you for being a valued colleague and friend. Pfizer will miss you, but on behalf of all of us, I wish you all the best in the next part of your journey. Thank you, everyone, and have a great rest of your day.

Operator

This concludes today's conference. You may now all disconnect.