Q4 2020 Earnings Call

Company Participants

- Albert Bourla, Chairman and Chief Executive Officer
- Angela Hwang, Group President - Pfizer Biopharmaceuticals Group
- Charles Triano, Senior Vice President, Investor Relations
- Chuck Triano, Senior Vice President, Investor Relations
- Frank D'Amelio, Chief Financial Officer and Executive Vice President, Global Supply
- John Young, Chief Business Officer
- Mikael Dolsten, Chief Scientific Officer and President, Worldwide Research Development and Medical

Other Participants

- Chris Schott, Analyst
- David Risinger, Analyst
- Geoffrey Porges, Analyst
- Gregg Gilbert, Analyst
- Jason Zemansky, Analyst
- Louise Chen, Analyst
- Navin Jacob, Analyst
- Ronny Gal, 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 Fourth Quarter 2020 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.

Charles Triano {BIO 3844941 <GO>}

Thank you, operator. Good morning everyone and thanks for joining us today to review Pfizer's fourth quarter and full year 2020 financial results, our 2021 financial guidance, 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, Development and Medical; Angela Hwang, Group President Biopharmaceuticals Group; John Young, our Chief Business Officer; and Doug Lankler, our General Counsel.

The slides that will be presented on this call were posted to our website earlier this morning and are available at pfizer.com/investors. You'll see here on Slide 3, 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 of course are subject to risks and uncertainties.

In addition, we'll be using 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 we will move 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 good morning everyone. 2020 was a year like none other in Pfizer's history with the separation of Upjohn complete, we saw the culmination of Pfizer's decade long conversion into a pure-play science innovation focused company. Through our collaboration with BioNTech, we deliver the world's first breakthrough COVID-19 vaccine in less than a year. And by harnessing the power of a variety of digital capabilities we made sure that despite the lockdowns and travel restrictions, we continue to serve patients around the world who rely on our medicines and vaccines.

Despite this challenging environment and the incredibly -- an incredible amount of resources we devoted to develop a safe and effective COVID-19 vaccine, we generated 8% operational revenue growth for the year from our core biopharmaceutical product portfolio, excluding the revenue impact from consumer healthcare and excluding $154 million in sales of the Pfizer BioNTech COVID-19 vaccine that were recorded in the fourth quarter. Keep in mind that this 8% operational growth includes a negative 2% impact due to the slowdown in macroeconomic and healthcare activity resulting from the pandemic. This operational growth was driven primarily by continued strong performances from Vyndaqel/Vyndamax, Eliquis, Oncology Biosimilars, Ibrance, Prevenar 13 outside the US, Inlyta, Xeljanz and Xtandi. So basically all the growth drivers contributed significantly.

Full year adjusted diluted EPS was $2.22 up to end the percent operationally from 2019. I would like to point out that the revenues and expenses associated with the Upjohn business have been re-categorized as discontinued operations and excluded from our adjusted results. So overall, we had a strong year, which positions us well as we begin to operate as one global focused biopharmaceutical company, which I have envision for the past several years.

Let me start with a discussion of some of our key growth drivers. Vyndaqel and Vyndamax generated revenues of $1.3 billion in 2020, up 170% operationally. Our disease education efforts continue to support appropriate diagnosis, increasing diagnosis rate to move the 21% at the end of the fourth quarter as compared with approximately 2% before relaunch from 2% to 21%. As of December 31, more than 20,500 patients have been diagnosed, more than 40,500 patients have received prescription and more than 8,500 patients have received the drug, including patients who received the drug at no cost through our patient assistance programs. We continue to see recovery in new diagnosis since Q3 and the gradual rebound in new patient starts with the current resurgence of COVID-19. However, we are seeing varying levels of regional lockdowns that could impact this recovery.

Eliquis delivered another strong performance in 2020 with revenues up 18% operationally to $4.9 billion for the year. In the US, strong volume growth was partially offset by a lower net price due to an increased number of lives in the Medicare coverage gap and the expansion of that gap, as well as unfavorable channel mix. Revenues from our global biosimilars product portfolio grew 68% operationally and totaled approximately $1.5 billion for the full-year 2020, making them a meaningful contributor to our growth. This was driven primarily by our oncology biosimilars, which grew 203% operationally, generating revenue of $866 million.

Global Ibrance revenues increased 9% operationally to $5.4 billion in 2020. Ibrance continues to be a leader in the CDK4/6 inhibitor class for metastatic breast cancer. In fact, 8 out of 10 first line HR positive HER2 negative metastatic breast cancer patients in the US who are prescribed a CDK4/6 inhibitor received Ibrance. This is a testament to the continued benefit Ibrance delivers to patients with its compelling safety and efficacy profile. Based on the continued strong prescribing patterns, Ibrance compelling safety and efficacy profile and more than five years of use in every day clinical practice with continued positive patients and physician experiences, we remain confident in its future performance of the metastatic setting.

Global Prevnar 13 revenues were up 1% operationally to $5.9 billion in 2020. Revenues outside the US grew 13% operationally in 2020, driven primarily by increased adult uptake in certain international markets, resulting from greater vaccine awareness arising from the COVID-19 pandemic. Although I should note that Prevnar 13 is indicated for the prevention of pneumonia resulting from pneumococcal bacteria not SARS-CoV-2, strong pediatric uptake in China also contributed to this growth. In light of the strong 2020 performance, growing revenues 66% operational.

For the full-year 2020, global Xeljanz revenue grew 9% operationally to $2.4 billion. The underlying prescription demand in the US grew 12% in 2020 compared with 2019,

outpacing the advance therapy market by 9%. We have invested in formulary access in the US, which played a vital role in enabling this volume growth. Last week, we reported top line data from a post-marketing safety study, which did not meet the non-inferiority criteria for the co-primary endpoints of MACE and malignancies, excluding non-melanoma skin cancer versus TNFi. We are continuing to analyze the secondary endpoints of the study and we'll discuss the full data set as well as the potential implications to labeling with the regulatory agencies. At this point, it is premature to make an assessment as to what impact this data may have with Xeljanz but of course patient safety remains our priority.

For Xtandi, alliance revenues for the US were up 22% for the year and when combined with our royalty income from ex-US sales totaled $1.4 billion. Xtandi new patient starts grew 12%, bolstered by the successful launch of the metastatic castration-sensitive indication which is helping patients earlier in their disease who will benefit from a longer duration of therapy. Of course, the biggest story of 2020 for Pfizer was our work with BioNTech to develop and deliver the world's first COVID-19 Vaccine authorized for use in developed markets. It took us just 248 days to get from the day we announced our plans to collaborate with BioNTech to the date we submitted to the FDA for Emergency Use Authorization. And I couldn't be more proud of how our colleagues stepped up when the world needed us the most.

Our ability to move at such extraordinary speed while always maintaining our focus on quality and safety, was the first powerful display of what the new Pfizer is capable of. While we never imagined a pandemic of this magnitude, every action we have taken over the past several years has been to transform Pfizer into an agile scientific powerhouse capable of addressing the world's most devastating diseases like the one that happened now. The manufacturing and distribution of our COVID-19 vaccine have gone very well as well. Not only did we achieve our commitment for 2020, but as of January 31, we had supplied 65 million doses globally, of which 29 million doses were supplied to the US government. We are continuing to work closely with the US government on our production release and shipping schedules to help states ensure Americans receive their first and second doses to the vaccine on time.

We have provided the government with a specific forward looking schedule, so they can plan accordingly. We foresee no issues with delivering the commitments we have made and expect to deliver 200 million doses to the US, by the end of May, two months earlier than our contractual obligation. Because of the dire need to vaccinate more people, we have explored innovative plans to create, increase the number of doses, we are able to produce globally by the end of 2021. As a result, we now believe that we can potentially deliver at least 2 billion doses in total by the end of 2021. This is based on the updated six dose label continuous progress improvements and expansion at our current facilities, and contingent upon adding more suppliers as well as contract manufacturers.

We are now approaching a year since the beginning of the pandemic. Based on what we have seen so far, we believe it is increasingly likely but a durable COVID-19 vaccine revenue stream like it's happening in flu is a potential outcome, for a couple of reasons. First there likely will be a need to boost regularly to maintain high levels of vaccine elicited immune response. Second, and maybe more important, we may need to boost to

counter the threat of the emerging new constraints, we have seen with variations in the spike receptor binding domain side. Genetic mutations occur natural during virus replication and spread. We recently announced results of in-vitro studies that show our sera from people who have received our COVID-19 vaccine effectively neutralized the virus bearing the SARS-CoV-2 UK variant spike and also neutralized engineered SARS-CoV-2 with key mutation from South Africa variant and UK variant spikes.

We are encouraged by this early in-vitro study findings, and we'll continue to monitor our vaccines effectiveness in preventing COVID-19 caused by the virus strains in circulation. We are waiting data on neutralization of an engineered SARS-CoV-2 with the full set of new patients from the spike of the South Africa variant. That said, there is an increasingly probable scenario when it could become necessary within the next few years to boost COVID-19 vaccinated patients with the vaccine encoding a spike variant. One of the reasons Pfizer and BioNTech chose to utilize an mRNA platform, is big growth of the potential for the flexibility of the technology in comparison to traditional vaccine technology.

This flexibility, includes the ability to alter the RNA sequencing the vaccine to potentially address new strains of the virus, if one develop -- if one even ever were to emerge, but this is not covered by the current vaccine. Of course, this requires additional development work and regulatory submissions and approvals. Pfizer and BioNTech are preparing for such a possible scenario by working closely with regulatory agencies as well as relevant scientific bodies to enable vaccine technical committees to review date and make appropriate updates to the coming days. Regarding other applications of the mRNA platform, we are advancing plans to deploy this technology for flu vaccines and may explore other opportunities to work on other viral diseases and other therapeutic applications outside infectious diseases.

Turning now to our 2021 guidance. I want to share just a few projects, Frank will go into more detail. The midpoint of our 2020 revenue guidance range reflects 6% operational growth compared to 2020 if you exclude completely the impact of our COVID-19 vaccine. While there are signs of COVID-19 may be here for some time, which could result as I said in a more recurring revenue stream. We are carving out the COVID-19 vaccines revenue for now. Frank will provide some context on both our anticipated COVID-19 revenue and margins in his remarks. While the COVID-19 vaccine has created a new cash flow stream, there is no change in our capital allocation priorities. We remain focused on growth initiative and the growing dividend though at the slower rate.

Now let's turn to the pipeline, which is the engine for the new Pfizer and continues to be one of our great strengths. As discussed during last September's Investor Day meetings, we still see an appreciated potential in our pipeline, particularly in our rare disease, vaccine and internal medicines R&D portfolio. I would like to start with highlighting the incredible improvements we have driven in our clinical success rates and how they compare with industry benchmarks. Between 2015 and 2020, our Phase 2 success rate on a five-year rolling average, more than tripled from 15% to 52%, which is almost double the 2019 industry benchmark of 29%. Significantly, most of these successes are either first-in-class assets of innovation build on established mechanism with novel scientific designs.

Our Phase 3 success rate on a five-year rolling average, improved from 70% to 85%, 13 points higher than the 2019 industry benchmark of 72%. And our end-to-end success rate more than quadrupled from 5% to 21%, almost triple the 2019 industry benchmark of 8%. I would also point out that while our Phase 1 success rate on a three year rolling average stayed flat at 48%, this is 8 points higher than the 2019 industry benchmark. We believe these metrics demonstrate that through our science we are selecting assets to move through the research and development process, but we have the best chance of benefiting patients. This did not happen by accident, but was a result of a purposeful R&D turnaround strategy, that we begun in 2011. We aim to sustain this success rate which we believe clearly demonstrates the value of our pipeline. In rare diseases we achieved two Phase 3 study start since our last earnings call. On November 23, we announced the third participant has been dosed in the Phase 3 BASIS study of marstacimab, an anti-tissue factor pathway inhibitor being evaluated for the treatment of people with severe hemophilia A or B. On January 7, we announced we had closed, we had dosed the first participant in our Phase 3 Duchenne muscular dystrophy gene therapy program. The CIFFREO trial is expected to enroll 99 ambulatory male patients ages 4 through 7 across 55 clinical trial sites in 15 countries.

Our DMD program is the first gene therapy to start the Phase 3 trial with a potential first and best-in-class profile. In inflammation, our unique ritlecitinib the JAK3-TEC selective oral small molecule has reported positive top line results in two Phase 2 studies, one for vitiligo and one demonstrating strong clinical remission rates in ulcerative colitis. Data from both studies will be presented in scientific congresses later this year. Last October, we announced FDA and EMA filing acceptance of our applications for abrocitinib in patients with moderate to severe atopic dermatitis with a priority review PDUFA day for the FDA in April. There is a large unmet medical need here, many of the 60 million patients are not well controlled on current therapy or are simply unfit and we see an attractive opportunity to capture many of these patients. In other words, we are not just looking to convert existing patients from other therapies.

In vaccines, the FDA had accepted for priority review, the Biologic License application for our investigational 20-Valent Pneumococcal Conjugate Vaccine for adults 18 years of age and older, with a PDUFA date expected in June. If approved, we believe the vaccine could provide the most comprehensive coverage against pneumococcal disease in adults compared with the standard of care and other pneumococcal conjugate vaccines in late stage clinical development. In internal medicine, we are progressing potentially novel treatments that address underlying causes of metabolic diseases and cardiovascular risk. We initiated a Phase 2b clinical trial to evaluate Vupanorsen for the potential to reduce cardiovascular risk and treat severe hypertriglyceridemia.

Our Phase 2 diabetes trial for our oral GLP-1 is enrolling rapidly and we expect to initiate a Phase 2 trial for obesity shortly. We expect a proof of concept readout in the third quarter of this year which will inform the next step, the potential pivotal Phase 3 program. In Oncology, we recorded robust response rates for Braftovi in the Phase 2 ANCHOR first line colorectal cancer study and have initiated a Phase 3 pivotal trial. We also achieved a positive readout for talazoparib in DDR+ metastatic castrate-resistant prostate cancer in the Phase 2 TALAPRO-1 trial which gives us increased confidence for a potential positive

outcome of the pivotal Phase 3 TALAPRO-2 trial, which has an expected readout for all comers in 2021 and subsequently for the DDR+ subsequent patients.

We are very excited about Elranatamab, our investigational BCMA/CD3 targeted bispecific antibody for the treatment of multiple myeloma. In December, we presented encouraging data from our ongoing Phase 1 trial, that demonstrated high response rates and manageable safety in patients with relapsed or refractory multiple myeloma, including a few patients who relapsed on or progressed after prior BCMA targeted therapies. In late January, elranatamab received Fast Track Designation for treatment of patients with multiple myeloma who are refractory to at least one proteasome inhibitor, one immunomodulatory drug and one anti-CD38 antibody. We recently initiated the potentially registration enabling Phase 2 trial of elranatamab monotherapy in triple class refractory multiple myeloma and we anticipate the first patient to be dosed this month. As you can see tremendous, tremendous activity.

Before I close, I want to say a few words about affordability. As we have said, our breakthrough medicines and vaccines won't do anyone any good if people can't affordably access them. We believe the industry has generated a great deal of goodwill with Congress and public opinion through our COVID-19 treatment and vaccine efforts and we hope we can build on this goodwill by working together on a solution, including making a contribution as an industry through legislation or executive action that results in lower out of pocket cost to patients. The status quo simply won't cut it, and we look forward to working with the Biden administration and members of Congress from both sides of the aisle to help ensure our breakthroughs are accessible to all.

In summary, 2020 -- in summery, 2020 was a transformational and very successful year for our company. And we look forward to sustaining this momentum in 2021 and beyond. We remain focused on being nimble and investing in our R&D organization so we can build on the strong improvement in key metrics we have seen over the past five years. We continue to expect a revenue CAGR of at least 6% on a risk adjusted basis, through the end of 2025 and double-digit growth on the bottom line. I would note that these projections do not include any potential impact from our COVID-19 vaccine. We remain very confident in our ability to achieve this growth rate 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 enhance our long-term growth prospects post 2025. We will focus mainly on smaller deals that fit within our current therapeutic areas, and as always, we are focused on value generation for Pfizer shareholders not those of potential acquisition targets.

Now I will turn it over to Frank to provide details on the quarter and our outlook for the remainder of 2021. Frank?

Frank D'Amelio

Thanks, Albert. Good day, everyone. I know you've seen our release. So let me provide a few highlights regarding the financials. We again saw a very solid revenue growth for the business in the quarter and the year, which continues to support our projected 6% plus revenue CAGR through the end of 2025. As a reminder, this growth projection excludes

any contribution from the COVID vaccine. In terms of the price and volume mix for the year, the go off of the 8% operational growth we posted excluding consumer healthcare and the COVID vaccine, or underlying biopharmaceuticals portfolio generated 10% volume growth, offset by a negative 2% price impact. So continued very strong volume overall.

Foreign exchange had a slightly positive impact on revenue in the quarter with a 1% benefit for the full year, while for the full year, we saw an overall negative impact of 1%. So 1% positive for the quarter, 1% negative for the full year.

Now moving down to the income statement. Adjusted gross margins were lower in the quarter, mainly due to the negative impact of foreign exchange, product mix and unfavorable year-over-year impact of cash flow hedging on inventory and COVID related expenses. However, it's important to note that on an annual basis, adjusted gross margin for 2020 was within 90 basis points of 2019 and around 80%. Adjusted SI&A expenses in the quarter were lower by 2% on an operational basis and lower by 10% on an annual basis.

There remain two main factors that drive the decrease for the year. The exclusion of consumer health and lower selling expenses due to Covid and to a lesser extent, the early implementation of a planned reduction in spending associated with our corporate enabling functions. Adjusted R&D expenses grew 24% in the quarter and 15% for the year on an operational basis. This growth was primarily driven by our investment in developing the COVID-19 vaccine. Reported diluted EPS for the quarter was up significantly compared to the prior year quarter mainly driven by lower asset impairment charges compared to the year ago quarter.

For the year, reported earnings were lower mainly due to the non-recurrence of the gain on the consumer joint venture formation in 2019. And adjusted diluted EPS grew 17% for the quarter and 20% for the year on an operational basis. I'd add that our full year adjusted diluted EPS was $2.22, which is below the range of $2.28 to $2.38, we had given in terms of new Pfizer financials on a full year basis. I just want to remind you that we had indicated on last quarter's earnings call that our actual reported numbers would be lower than the guidance because the guidance assume full-year of operating without Upjohn as well as assuming a full year benefit of transitional service agreement recoveries and lower interest expenses from the deployment of the $12 billion in proceeds to pay down debt. So with the deal not closing until November, we only had a small benefit from these factors in our reported 2020 financials.

Now let's move to our 2021 guidance. We provided total company guidance, which includes the Covid vaccine and then we provided some additional subledger detail on our assumptions regarding the projected Covid vaccine contribution. So you can also get a read on the business without (Technical Difficulty). In terms of revenue, we are projecting a range of $59.4 billion to $61.4 billion, which includes a foreign exchange benefit of approximately $1.4 billion. And at the guidance range midpoint represents operational growth of 41% from 2020. For adjusted cost of goods, the range is 32% to 33% as a percentage of revenue, which incorporates the Covid vaccine gross profit share payment to BioNTech as well as some other related items I will speak to in a moment.

On SI&A what we see is the impact of increased sales and marketing expense behind key growth brands as well as the expected product launches that are enabling function cost savings. In addition, we see growth in R&D, which follows along with our pipeline development cadence and I note given our clinical trial success metrics Albert referenced, we're confident that are making sound R&D investments. Adjusted other income and deductions is projected at just over $2 billion of income. In addition to the usual items included here, remind you for modeling purpose there are three larger items in terms of income are our GSK Consumer Healthcare joint venture equity income, their dividend income and transition service agreement recoveries, primarily related to the interests.

Working this through with our projected 15% tax rate yields and adjusted diluted EPS range $3.10 to $3.20 or 38% operational growth at the midpoint. This range is a bit higher than what we discussed three weeks ago and was driven mainly by an increase in our Covid vaccine sales projections since then. Let me offer some assumptions in context on the projected Covid vaccine financial contribution and our collaboration agreement. The Pfizer BioNTech vaccine collaboration construct is a 50-50 gross profit split. Pfizer will book the vast majority of the global collaboration revenue except for Germany and Turkey, and we do participate in China. We continue to expect that we can manufacture up to 2 billion doses in 2021.

However, given historically in the year, we are not projecting that we will sell all those doses. Ultimately, we may contract all the doses, but for the purposes for our initial guidance, we primarily included doses that are covered by strong supply agreements with various governments. From this we currently forecast approximately $15 billion in Covid vaccine revenue is which is what you see here. Given we remain in negotiations for additional contracts, we are not providing the number of doses behind the revenue wise. Our cost of sales for the Covid vaccine revenue will include manufacturing and distribution cost a royalty payment allowance as well as the payment to BioNTech representing the 50% gross profit split.

All in, this yields and anticipated income before tax, Covid vaccine in the high 20% range. Let me add that if we contract for additional -- if we contract for the delivery of additional doses during the year, we provide a guidance update in our subsequent earnings releases. If we remove the projected Covid vaccine contribution and related impacts on revenue, that results in our business, having 2021 projected annual revenue between $44.4 billion and $46.6 billion, so 6% operational revenue growth at the midpoint and about 8% if we include the current favorable impact of foreign exchange compared to last year.

In terms of adjusted cost of goods, net of the Covid vaccine, we see a range between 21% and 22% as a percentage of revenues. For adjusted diluted EPS, we see a range of $2.50 to $2.60, which represents a 11% operational growth at the midpoint. These growth rates are all consistent with how we've been publicly positioning the business subsequent to the Upjohn separation. In terms of reporting our quarterly earnings, we are not going to report two sets of financials, one with Covid and one without. But I think the context in terms of the vaccine, margins will be helpful in calculating a good estimate of the (inaudible) the adjusted diluted EPS impact based on the Covid vaccine revenue we will report in future earnings releases.

Let me speak for a moment about our dividend going forward and how it will initially be linked to the interest dividend once it is declared. To make it simple, let's start with Pfizer's current annualized dividend rate of $1.56 per share. A Pfizer shareholder owning 100 shares just prior to the spin-off, would now still own their 100 shares of Pfizer and also 12 shares of Viatris assuming they have continued to hold Viatris shares. The 100 shares of Pfizer would generate $156 in annual dividend income and currently 12 shares of Viatris do not generate any dividend income. This $156 in annual dividend income is what we will preserve.

Once Viatris declares its dividend, we will calculate the annual income generated by the 12 shares of Viatris and then adjust the Pfizer dividend. So the combined annual income generated from the 100 shares of Pfizer and 12 shares of Viatris totals at least that $156 in 2021. So 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. I hope this example is helpful.

In summary, we had a strong 2020. The separation of Upjohn is behind us. The business is on track for solid top and bottom line growth. And we are highly focused on advancing our pipeline, supporting end market brands and looking to deploy capital responsibly would have focus on initiatives that can solidify our long-term revenue and earnings growth.

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

Chuck Triano {BIO 3844941 <GO>}

Right. Thank you Frank and Albert for the prepared remarks. Operator, at this point, can we please poll for questions. Thank you.

Questions And Answers

Operator

(Operator Instructions) Your first question comes from the line of David Risinger from Morgan Stanley.

Q - David Risinger {BIO 1504228 <GO>}

Thanks very much. So first of all, congrats on the phenomenal vaccine progress and the benefits that Pfizer is driving for society, that's much appreciated by everyone on this call and beyond. My two questions relate to vaccine prospects and Xeljanz. So, first, could you speak to how you are projecting the vaccine sales for (Technical Difficulty).

A - Albert Bourla {BIO 18495385 <GO>}

David, unfortunately you are cutting often. I couldn't hear you. Can you repeat the question on the vaccine from the beginning?

Q - David Risinger {BIO 1504228 <GO>}

(Technical Difficulty)

A - Albert Bourla {BIO 18495385 <GO>}

Unfortunately, the line is not good, David. We can't hear you.

A - Chuck Triano {BIO 3844941 <GO>}

Maybe Dave, you can come back in. Operator, can we move to the next question.

Operator

Your next question comes from the line of Steve Scala from Cowen.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. I have two questions. In what scenarios would you not sell all 2 billion doses of Covid vaccine, Pfizer can manufacture in 2021? Some competitors haven't exactly exceeded expectations and only a small fraction of global demand has been satisfied to date. So it seems as though you saw every dose you make in that the current guidance is going to be way low. Second question is, on the Xeljanz CV study, should we assume DVT tracked similarly to MACE? And given that Pfizer has other JAKs in development, what do you believe are the long-term implications for JAK class -- for the JAK class overall given this recent Xeljanz CV study?

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Steve. Let me take the Covid one and then I will ask Mikael to comment on the Xeljanz first part and then Angela on the implications on commercial. And Steve, we try not to give a low expectation, try to give a responsible expectation. If you're asking if there is a scenario that we will sell everything? Yes, there is. Also, I would tell you that if that was an open market, which means that the physicians and citizens, they have the ability to choose which vaccine they will receive, I would feel very comfortable that we will have the lion market share because we are first and we are best, as you have clearly indicated and we have great operations in basically every country in the world.

But this is not an open market at least for this year. This year, it is a market I think it is controlled by governments appropriately because I think we are in a crisis as you know, and also, it is a market that creates a lot of political pressures. So not always the decisions are sound, solid and avoiding panic. So with that in mind, we have a formula that we try to implement in a responsible way but takes into consideration, the contracts -- the potential for future contracts but also takes into consideration the strength of the contracts, takes into consideration the potential for other vaccines to present data. And in fact the reason why we changed our revenue projections was resulted in (Technical Difficulty) which resulted in $0.10 improvement in our bottom line. It is because we did have more news from the AstraZeneca registration in the way that it is perceived in Europe. We heard the news from (inaudible) reported data.

We have much better visibility now in the last two weeks on the manufacturing capabilities. All of that resulted in us increasing our projection. Clearly, there are a lot, if this is a multi-dimensional and let's say challenge to have accurate projections and clearly, we are having dynamic changes, which we will follow and we will update our estimates as time comes. But in all honestly I couldn't responsibly just say right now we are going to sell everything we can make the $2 billion, when we have all this dynamic situation, that it is evolving.

Now, why don't we move to Mikael to talk a little bit about the MACE and Xeljanz and then Angela on this revenues expectations.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you, Albert, and Steve for the question. As you know, the 1133 study for Xeljanz was rather unique population with increased either risk. Now Xeljanz has been started in numerous clinical trial, and in the market where a large population have used it in a more general or a population or in ulcers colitive. And in those populations, it has had a very robust efficacy to safety profile. I think RA by itself has more, see the liabilities that standard RA patients and this was a very specific subset.

Now going to other JAK inhibitor, the next generation of JAK inhibitors such as abrocitinib in registration for a atopic dermatitis or as Albert reported ritlecitinib which is a unique JAK3-TEC inhibitor, each JAK inhibitor differ by itself. And we think both of these two that I mentioned, had a very encouraging benefit to risk profile. And while regulatory agencies have, in some instances inferred general class label cross JAKs, I think the experience will tell that abrocitinib for atopic dermatitis has a very compelling efficacy and risk profile and ritlecitinib for alopecia that's reading out later this year or for vitiligo and with ulc colitis where we have very incurring Phase 2 data, again as a unique profile. So I don't think that we should extend 1133 to other JAKs and I think we also need to look at Xeljanz having a very robust profile in populations that was not the smaller version of the 1133 study. Thank you very much.

A - Angela Hwang {BIO 20415694 <GO>}

Thanks, Mikael. And then just building off of what Mikael has said, as you know, we have a very robust data set that has been built around Xeljanz for over seven years, 50 clinic different clinical trials, 260,000 patients that are currently on Xeljanz. And of course a very robust real-world -- real-world dataset that goes along with these 260,000 patients. So I think based on all of this and together with the fact that we are still so early on in our understanding of the 1133 data as it pertains to Xeljanz, that we feel confident that Xeljanz will remain an important part of the treatment paradigm for RA patients and for patients with a PsA. And you see as well and that it has an appropriate and favorable benefit risk profile for this sort of patient population type.

And so of course we will share the data with you, and as we continue to learn more about this study, but for now, that's how we see it. And then I think you had one more question in terms of how do we think about this in terms of impact on our other JAKs. And as Mikael said, scientifically each one of these molecules are very different, and they are all being designed with a different benefit risk profile to match the different disease

condition, as well as the different patient type. And so I think, as a result, we continue to be very confident about our JAK portfolio and the investments that we're making in each one of these, and we think what we will be able to deliver our differentiated profiles that will be appropriate and fit for purpose for that condition, and for that patient population [ph]. Thank you.

A - Charles Triano {BIO 3844941 <GO>}

Thanks for the responses. Next question please operator.

Operator

Your next question comes from the line of Gregg Gilbert from Truist Securities.

Q - Gregg Gilbert {BIO 3565226 <GO>}

Thank you. Albert, it seems pretty clear that Pfizer, the stock anyway is not getting a whole lot of credit for the COVID-19 vaccine. And whether or not you agree that that's fair. I'm curious how you expect to leverage the expertise you've built in this area, into areas that investors might view as contributing more to long-term franchise value regardless of what happens to the COVID-19 part of the story.

And then a second vaccine related question perhaps for Angela. There's been a lot of focus on your vaccine and others about logistics and supply and coverage of variance. But it seems to me that at some point a key metric, if not the most important metric will be how many people want to get a vaccine. So curious what your work tells you on that front and whether you plan to get involved as a company and helping drive awareness and demand at some point or is that not really Pfizer's role to play? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Gregg, thank you very much. I fully agree with you that I don't think we are receiving a lot of credit, no further vaccines right now when you sort of stock price but mainly for our basic business and pipeline. This is a business that is growing 6% in double digit, the bottom line excluding any COVID. And clearly deserves much higher multiple in this industry. The same comes even more when you speak about the COVID-19 vaccine. But I think clearly people should see much more into that.

So to your question how do we plan to use strategically this platform? I believe that the RNA technology has been proven in a glorious way but will have an impact in treating diseases, in preventing diseases in multiple applications. And I believe Pfizer has accumulated expertise and knowledge of a decade into one year. And also Pfizer has completed infrastructure investments that will take five years, again into one year. So clearly we plan to use these expertise so that we will be able to benefit more and more patients. I made some comments that within the COVID vaccine, I believe that COVID is -- the dynamics in the COVID more and more indicate the potential, but we will have a clearly repeated business.

The reasons for that are multiple. Let me start by saying in the beginning, we were waiting to see if the immune, it will be durable. Now we still don't have data about the immunic of our vaccines because it is early, but we do see that the people that have disease, more and more publications indicate that after several months their immune respond goes down, so there is a need to boost. Also there are a lot of papers that have been published that indicate even for the new variants that if you have very high level of the immune responses, you are protecting against those variants in much higher level than you have lower levels of these antibody. So that indicates that the need to boost so that you maintain much higher levels into that.

And last but not least, it is clear that the scenario that the variants will develop in such a way that they may be escape in very effective protection from the current vaccine, which is not the case right now for us. Then we will clearly preparing ourselves so that we will produce in a very speedy time. I made publicly a statement that that needs to be done and to end in less than 100 days to provide new booster vaccines that will protect against the new variants. So, in scenarios like that and even in scenarios that the Covid will move from a pandemic into more of a normal type of vaccination business, it is very clear that Pfizer will have a key advantage, not only because of the strength data but also because we have developed significant brand equity and trust with the people when it comes to their choice. We have infrastructure and expertise that will help us.

RNA is not going to provide only COVID-19 vaccines. We are accelerating our work for flu right now and we are clearly investigating multiple other applications in other vaccines for this RNA technology or therapeutic areas. So I believe that our business excluding Covid is very robust with robust pipeline. But I think Covid has a very good chance but could completely transform the revenue and earnings trajectory of this business starting from now.

And with that, I will ask Angela to comment on the question about again the Covid vaccine. Angela?

A - Angela Hwang {BIO 20415694 <GO>}

Thanks for the question. And I think what you're talking about is vaccine confidence, which clearly has been a big topic since the vaccine was introduced. And I'm actually really encouraged by data that we're receiving on a routine basis that is demonstrating that vaccine confidence is indeed building and that compared to where we were even a month ago, we had a significant rise in interest and willingness of the public to get vaccinated. And I think a lot of this is driven obviously by real-world, experienced by many people who are now getting the vaccine and having good experiences with them. So I think that this will continue.

To your question about what is it that we're doing to drive awareness and demand? I think first of all we have to understand that right now we are in a period where we are operating under an EUA, the emergency approval. So there is guardrail as it pertains to that and what it is that we can do. For sure, we have worked very diligently with many, many, many medical and public health societies and institutions to ensure that we are supporting education across the entire country. There recently was even a public service

announcement that was launched where it had our support in conjunction with a number of patient advocacy groups to really educate and to create confidence for the public around this vaccine.

In addition to that at a more specific level, Pfizer uniquely has really supported the healthcare professional community in its vaccinations by providing a lot of training, a lot of support to ensure that confidence is gained at the vaccinated site and actually just to share that over 30,000 HCPs have been trained by Pfizer alone in the recent month or so to be able to confidently vaccinate these -- vaccinate people and I think that that's also helping to create confidence. But of course where we can get most involved and we'll be able to do even more is once we receive the BLA. And so we're working towards that and we will build on the education initiatives that we already have in place that we'll be able to our amplify that even more once we have a full label. Thank you.

A - Charles Triano {BIO 3844941 <GO>}

Thanks, Angela and good point on the BLA opening up more opportunities. Next question, please, operator.

Operator

Your next question comes from the line of Terence Flynn with Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Great. Thanks so much for taking the question. And thank you for all the work you're doing again on the Covid vaccine. I was just wondering, is there an integrated system that's being set up by either the government or governments to Pfizer to monitor instances of vaccine breakthroughs and conduct sequencing? And then what factors and who will ultimately dictate when a change in the potential of the vaccine is needed to cover an emerging variant? How does the consensus emerge on that question? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Yes, Mikael, would you like to take this question, please?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. There are different -- organized at the government level efforts. In the US, the position or sequence is both to track new strains like South Africa and Brazil, as well among un-vaccinated and vaccinated or deposited in certain databases. There is one initiative in UK and then of course Pfizer has the unique collaboration in real world evidence with the Israeli ministers of Health which will allow us to track first real world evidence for our vaccine in the population. And as you may know, we are the number one to have such data that shows 92% to 95% in real world evidence vaccine efficacy primarily seen initially in an older population that's order normally to get a stunning data. And it also showed a very low 0.25 about for both 24 and 26 for first and second injection of adverse events.

So really well performing large population of millions of individuals. And of course, they will also, in fact if there are breakthrough infections. Now, in general, I think there's been claim that the South African and Brazil variants are more difficult to treat. And vaccines that have lower antibody levels will have much more breakthroughs given that the mRNA vaccines have a high antibody levels and that was I think implied in Albert's answer. We expect them to be much more resistant to breakthroughs for longer time.

And I think data from several lab shows that if you maintain with mRNA vaccine high antibody levels, you will actually protect very well even against dose variants and that suggest and we are just embarking on such studies that you could boost with the current vaccine a further time and avoid some of these breakthrough infections that were reported. Recently in some vaccine studies that would be our aspiration to demonstrate that by keeping individuals with very high titers, you can really impact and that can be recorded as you asked in various systems that are now in place in many countries and that could be a very important way to transit into a more sustained protection, sustained business model who are the moderating allow you to plan when the next boost should happen.

A - Charles Triano {BIO 3844941 <GO>}

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

Operator

Your next question comes from the line of Louise Chen from Cantor.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my questions. So my first question is, if the Covid vaccine becomes routine, how do you think governments and physicians will choose amongst these different vaccines that have received Emergency Use Authorization? And then how do you think about that 95% efficacy rate in light of mutations? And then last question is on your PCV20, if it's approved, what do you expect the ACIP recommendation to be or what would you ideally like it to be? And do you think there'll be any upgrade for those 65 plus do the additional serotypes? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Why don't we start with PCV20 and Angela then we can come back to Covid. Angela?

A - Angela Hwang {BIO 20415694 <GO>}

Sure. So in terms of PCV20, I mean what we believe, our value there is the additional serotypes. And that in adults, these additional serotypes are meaningful because it will give us 33% more protection against strains causing IPD in adults. And 42% more protection against strains causing IPD for pediatrics. So we feel that this is very value creating and provides us the opportunity to really bring an important option into the market that is an upgrade compared to what it is that we have today.

And then to your question about ACIP, of course, we're working closely with the FDA for approval and with the CDC at the right moments in time to get the right recommendation. We believe that the recommendation will be positive as it pertains to PCV20 and we look forward to working with them to achieve that.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. As regards the how people could choose or physicians could choose, if that is a routine? I believe that if this is a routine, the decision will come as with all other vaccines and medicines, the strength of the data. I think that this is why I made before the comments that given that we are first which means that we are vaccinating a lot of people right now with the first doses, given that we have set a strong safety and efficacy database in a open choice situation, we will get the much majority of the share of choices.

But what I think will come reality likely after in 2022 when the governments do their whole vaccination scheme and also in that year there will be I believe the capacity. So, volume would not be the case, even if everyone wants to get one vaccine I think will be enough to make this one vaccine. What about -- the 95% efficacy in terms of variants, I think we answered that, but Mikael may be you want to reiterate once more why the higher, the efficacy the better is not only for the current, but also for the variants.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, very brief, it's clear from convalescent plasma studies that now the last couple of weeks been out and also from plasma from vaccine recipient. Higher antibody level seems to protect from variants in the preclinical studies from patients. So I think it will project into the vaccines with high antibody levels and T-cell immunity which are an additional protection mechanism. We'll do very well again variant and keep boosting them, we'll keep the variance of the population for a longer time before there's any need to shift to variant selective. So, I think the data we have with mRNA vaccine put them really in a unique category, having the strong immune response, the ability to boost and ability to, if needed reconfigure.

A - Charles Triano {BIO 3844941 <GO>}

Right. Thanks, Mikael. Next question please, operator.

Operator

Your next question comes from the line of Umer Raffat from Evercore.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi guys, thanks so much for taking my question. I want to hit upon two different topics. One, as we think about possible new vaccine for the new variants, do you guys have plans in place, are you working on it right now? Should we anticipate some sort of Phase 1 data by at some point this early summer? And has there been a consideration allocate some of this $2 billion in doses capacity to a new version of the vaccine. And separately going back to the Phase 3 reported, it's been a few weeks. And one of the questions I've had is, of the patients that tested positive on the vaccine post dose 2, what did we learn about

what mutations those patients had on deep sequencing, what did we learn about their NAB titers and T-cells? And I wonder if there is anything we can draw on correlate of protection? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Umer, very, very good, excellent questions. Mikael, do you want take the last one. And also the first one and then I can speak then later on the manufacturing piece.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, with variants, we are embarking on a study, which will give a boost after six months and posted also compared with the 12 months, we will compare the wild-type, the current vaccine with a variant vaccine is likely based on the 484 amino acid from Brazil and South Africa. I think that given the date so strong with our vaccine, as we alluded to, may very well be the third boost at the proper time point is sufficient and you continue to monitor variant. But we will be prepared if needed, with data, as you said around early summer.

Quality protection is something we are working with a lot of scientist not just looking at data in our trial, but in public consortium with ANH looking at data across many trials and we will see the outcome. I expect again high antibody levels, plus seasonal immunity will provide the best durability and that makes us very optimistic about the unique profile of mRNA vaccine.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Mikael. And the 2 billion doses that we are speaking about, it is all clearly for this current vaccine and clearly also, we are working to see if we can improve that even further. But right now we are -- our commitment of 2 billion doses. But the reason why we had selected mRNA in the first place was because simplifies tremendous with this type of process, our ability with this technology to build a new consort of the same vaccine by just changing the RNA messenger RNA within this vaccine. It is really very, very simple process in terms of manufacturing, and in terms of actually developing it.

Now, nothing is simple in biology, when we speak about high complicated process, but relatively between another technology, this is very simple. So I wouldn't say that I would anticipate the MACE or if we have to go to a new vaccine that we will have a major set kind of take-up in our manufacturing capacity. I think overall 2 billion doses could be and maybe a little bit less if we start producing new vaccine replace altogether, the new variants. Altogether cumulatively new and the old if there is a need to do. Thank you.

A - Charles Triano {BIO 3844941 <GO>}

All right, thanks, Albert. We'll take our next question, please.

Operator

Your next question comes from the line of Geoffrey Porges from SVB Leerink.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you very much. And unfortunately will continue a little bit on this thing, Mikael, could you give us a sense of whether you think the so-called South Africa, and Brazilian variants that have similar mutations, represent terminal on a terminal adaptations of the virus or do you think that we will see sort of almost recurring an infinite adaptations that we may have to contemplate adapting vaccines too.

And then secondly, have you contemplated giving a single dose of vaccine to those who previously been infected given what's probably 20% to 25% antibody positivity in the US population. And lastly, could your nex-gen variant vaccine be refrigerated stable? Thanks.

A - Albert Bourla {BIO 18495385 <GO>}

Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you. Yes. The first, the strains like the ulca constrain was mainly selected for transmits ability to spread quickly. As there were previously infected people in South Africa and Brazil, the new strains have been selected for immune escape which is the 484 I mean as it is the most important.

High antibody titers as alluded to before from our vaccine, it seems still to be able to wrecked quite nicely with that strain always somewhat more moderate reduction and we think keeping high titer up in patients will be a very good trio throughput with approach until there is a need for a estranges. Now with that concept, keep up high antibody titer. You should immunize whether you have had infection or not twice. That gives you a maximum titer and allow you to fight of various strains for as long time as possible before you may need to boost or of the some time that there may be any reason to a variant vaccine as Albert alluded to and we are currently initiating study to understand when a third immunization would be helpful for participants and we will be starting 6 to 12 months as initial assumption. And of course we'll continue to make efforts to make refrigerated vaccine that includes localization or possible liquid with stabilized product. And we think end of this year or next year we'll have such a product.

A - Charles Triano {BIO 3844941 <GO>}

Excellent. Our next question, please, operator.

Operator

Your next question is from Vamil Divan from Mizuho.

Q - Vamil Divan {BIO 15748296 <GO>}

Great. Thanks so much for taking the questions. I mean I'll just shift gears a little bit off the vaccine, I guess somewhat titer vaccine, but little different angle here in terms of capital allocation, in Alberta and you're mentioning that no change your strategy that the vaccine obviously is going to give you a boost to your sales and cash flow at least in the near term

here. So, I'm just wondering, should we expect Pfizer to be maybe more active and complete more transactions in the coming months is to try and boost your pipeline, then you otherwise might have been or if not, I guess just then if you use for comment on your kind of thoughts around this added cash flow and what you might look to do there?

And then my second question is on Vyndamax where it looks like you are having pretty good traction there may be than we thought given the pandemic. I'm just wondering if you can maybe comment, so where this product is now relative to where maybe you would have expected a year ago, sort of pre-pandemic. I'm trying to get a sense there a real sort of bolus of patients are that you could maybe make more traction without the pandemic. Is this, or you already doing quite well in terms of gaining penetration into those patients. Now so just expect the same sort of uptake going forward. So any thoughts would be helpful. Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Vamil and thank you also for asking something outside Covid at least -- at least makes it very interesting. So you are right, the capital allocation, it is the result of our strategy. And if anything, the COVID-19 is proven our strategy, correct. It is I think a demonstration that we do have reserves MaSilva FESB [ph] resources of a big biopharma and the agility of a small biotech. I don't think that many people would bed that Pfizer would be the first one to complete something like that. But this is what we are building in the last few years and this is the demonstration that we have there.

So our capital allocation, we never say never, but right now the dividend will be maintained, Frank was very clear about it. A growing dividend, it is important thing, part of our investment thesis. And so we will continue in a very intensive reasons to try to bring in Phase 2, Phase 3 predominantly. Programs that through our R&D machine very quickly and very successfully can become medicines and vaccines that could generate revenues that would fill the gap but -- from the 6%, so we can sustain the 6% beyond 2025.

Nothing changes also, we do have higher flexibility in terms of cost with Covid, clear. But it is not that we were lacking cost before and we couldn't do basically things that we wanted to do. Now what makes it even more comfortable to do that. Still, I don't think because we have this comfort level. We will do things that do not respect the fact that these are shareholders' money. So we will investment very prudently, we are not going to spend but we are clearly ready to take risks when needed. And also clearly ready to pay a full price for things that we really want. And as I said before, we never say never.

So Angela how do you see Vyndamax evolving? Was that a bonus? Is this something that you continue growing? What is your views on that?

A - Angela Hwang {BIO 20415694 <GO>}

So we have been really pleased with what we've seen with Vyndaqel/Vyndamax and the patients that we have been able to diagnose. And I think this has gone better than we thought, actually even with the pandemic. Currently, this last quarter, we were able to diagnose 21% of the population with ATTR-CM. And so the increase that we've seen

quarter over quarter gives us a lot of confidence that our ability to diagnose and the imaging techniques that are being used, the non-invasive techniques are working really well. I would say the bolus is gone. That was something that was maybe in the first half of -- from the first half of the year when we launched.

And I think where we are now is in a pretty good cadence of using our suspect and detect techniques as well as the ability to refer to imaging centers to get the diagnosis and I think that our success rate in diagnosis is evidence of this. And so I think we'll continue to see cadence like this, about a course there's still massive opportunity, 80% more patients still to be diagnosed. And so we're really focused now on using technologies and different techniques to heighten and to look and to screen more effectively pull patients because once we know that once we can find them, they can get diagnosed. So that's where our focus is going to continue to be in 2021. Thank you.

A - Charles Triano {BIO 3844941 <GO>}

Right. Thank you, Angela and Albert for those responses. Let's move to the next question please.

Operator

Your next question comes from Tim Anderson from Wolfe Research.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. A couple of questions. On the mRNA platform, you talk about leveraging that technology and outside -- there is outside of a Covid vaccine. And I think you mentioned something like seasonal flu. I'm guessing timelines for any of those types of opportunities would be more normal. And I'm hoping you can kind of give us some idea just a rough timeline on when Pfizer and BioNTech might launch a non-Covid mRNA vaccine product totally unrelated to COVID-19? I'm guessing that would be something like five years wait at a minimum, but maybe you can shed some light on that.

And then second question just on guidance for 2021 and the other income line, a big number $2.2 billion very much above the normal run rate for that line item. You mentioned the consumer JV and NVIV and Viatris all going into that only brand new piece there is Viatris. So can you just give us more details, why that number goes so high in 2021? And importantly, what's the run rate for that line item beyond 2021.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much, Tim, obviously Frank will answer the second one and Mikael the first one. Let me also just make a introductory comment before I ask Mikael to speak about flu. I believe the Covid thing has created a new normal. I don't think it will -- we are aspiring here in Pfizer to go back in the old normal development timelines, even if we were as you saw before at the top of the industry benchmarks. Right?

So if Covid were not with for a cancer, Covid were not with flu. And I think that clearly with Covid was the collaboration of regulators, that made that also possible, but it was a lot of

other things that we have tested and we did differently than before. So our aspiration is that these learnings will be clearly applied to everything in our portfolio in our pipeline.

Now with that Mikael, tell us a little bit, how do you see the timelines? Where are we with the flu?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you, Albert, and I think you said it well that the type of light speed approach is with the mRNA platform should of course be projected into other areas, as well as flu. So, Tim, you mentioned 2025, I think that would be more conservative. And you know traditionally realistic goal and we are looking at ways to bring it as a potential product for approval earlier than 2025, of course, it depends on whether there are good flu seasons with the cases coming on along or not. And I think as the life continues with vaccinated folks, flu will take up new momentum. So our aim is ahead of 2025.

A - Albert Bourla {BIO 18495385 <GO>}

Terrific.

A - Frank D'Amelio

Albert, I'll answer on the other income question.

A - Albert Bourla {BIO 18495385 <GO>}

I'm sorry, other income. Yeah.

A - Frank D'Amelio

So, Tim, let me run the numbers first and then I'll answer the question. So you talked about the absolute size of the number in 2021 guidance. Remember in 2020, our other income was about $1.5 billion and adjusted results. So it's going from about $1.5 billion to the guidance we gave, which is about $2.2 billion. The major elements in the increase are really a transition service agreement recoveries and that's primarily now as a result of closing the Viatris transaction, higher joint venture income and then we had some pension expense benefits as well. Those are the pieces that really get us from the call it $1.5 billion in 2020 to the $2.2 billion of guidance in 2021

And then you asked about beyond '21. I think the way to think about beyond '21 just in terms of the cadence of the rhythm of that number is the watch item for us will be what happens with them, the consumer joint venture relative to what with GSK decides to do with their portion of that venture and we own 32% of that venture. So we'll have to see what GSK does. Obviously depending on what they do that could impact our other income number going forward beyond that.

So that's kind of, I'll call the watch item for us in that line item.

A - Charles Triano {BIO 3844941 <GO>}

Right. Thanks, Frank. Next question please.

Operator

Your next question comes from the line of Geoff Meacham from Bank of America.

Q - Jason Zemansky {BIO 21180757 <GO>}

Good morning, everyone. This is Jason on for Geoff. Real quickly, sorry to move back to Covid. But, Frank, if you could talk a little bit about the vaccine at least to the high level about how the marginal contributions will change over time as manufacturing scales? I just want to get a better sense of the intermediate to longer-term if COVID does ultimately transition to more of an endemic versus the pandemic? And then secondly, we wanted to ask about next steps for Xeljanz after the recent safety data. Is the assumption here that the label will include these new data? Thanks so much. Thank you very much. Frank?

A - Frank D'Amelio

So let me -- Jason, let me do it this way. Let me talk about kind of how the current margins work and then I'll pivot to how they can work going forward. So in terms of the current margins, I always start with we're in a pandemic pricing environment. So the one price that we published is the price with the US of $19.50 per dose. Obviously, that's not a normal price like we typically get for vaccine, $150 -- $175 per dose. So pandemic pricing. Then what are the takeaways from that?

Obviously there is the direct material, the labor, the factory overhead, shipping, distribution then obviously royalty assumptions we've made, then the 50% gross profit payment that we pay to our partner BioNTech. Then you layer in on top of that some marketing and sales expense, some medical expense, some R&D expense. And come out with the high 20s in terms of that as a percentage of revenue, what we guided to. That's kind of the existing financials for the year for the vaccine. Now, let's go beyond a pandemic pricing environment before the environment we're currently in.

Obviously, we're going to get more on price. And clearly, to your point, the more volume we put through our factories to lower unit cost will become so clearly there is a significant opportunity for those margins to improve, once we get beyond the pandemic environment that we're in.

A - Charles Triano {BIO 3844941 <GO>}

Thank you very much from, Frank. And then Angela, would you like also to take also the.

A - Angela Hwang {BIO 20415694 <GO>}

So, as it pertains to the label for Xeljanz, this is something that we don't have any -- we don't have any sense of yet. This is a big study, 1133 was a big study, five years 4,500 people. We only have the co-primary endpoints that we've shared with you, we still have a lot of work to do in terms of secondary endpoints sub-populations and bringing all of this

together to discuss this with regulators. So I think we're still a ways off in terms of really understanding what impact they will be to a label and that we will keep you posted.

A - Charles Triano {BIO 3844941 <GO>}

Right. Thank you very much. Thanks Angela, operator, let's say, let's take another question please.

Operator

Your next question comes from the line of Ronny Gal from Bernstein.

Q - Ronny Gal {BIO 15022045 <GO>}

Good morning everybody, congratulations on the very impressive progress on COVID. And I had two questions and they're both of things you haven't done. The first one is development of JAKs 4RA, obviously you've got a really versatile flat for them for developing JAKs and especially with an eye to the Xeljanz set issue, it seems interesting, it should be interesting for you to consider second generation JAK in that core largest INI market. So, any thoughts about development there and if there is, what will be the requirements fee.

The second one is about PD-1 approaches. You are participating in that market, somewhat tangentially if I have to put it that way, we've seen couple of the other large pharma companies like Lilly and Novartis bringing in PD-1 simply as a base platform for combinations or maybe as a low-cost alternative in the current markets. And we consider that approach, and where do you come out of this issue?

A - Albert Bourla {BIO 18495385 <GO>}

I think Mikael and John could provide some insights here. So Mikael why don't you start a little bit, it was more scientific information and then John you can summarize our strategy for docs and the PD-1 as a low-cost alternatives.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you. Our Ritlecitinib which is a completely unique JAK's retake inhibitor actually in a Phase 2 already did deliver really interesting profile. We have a study ongoing without the Phase 2 ritlecitinib by itself and combined with the second molecule Iraq war to see if we can do a step change improvement in RA. Please recall also that we just communicated at have had really strong data in also ros colitis [ph].

So that product could grow very strongly in IBD as an option, but we'll continue in RA. I'll say just something on our own PD-1 and maybe John can add to additional things we do global there. We have a very nice kind of best-in-class PD-1 platform, so ugemalimab that was developed in Pfizer that was subcutaneous and have delivered very nice response rates across multiple solid tumors. And we actually starting a Phase 3 with that one bladder cancer combining with BCG in order to improve outcome for those patients. Thank you.

A - John Young {BIO 17639257 <GO>}

Thank you very much for the question, Ronny. I think Mikael sort of touched on the key points. So then we'd really just sort of highlight that obviously we are -- we have our existing partnership on Vivanti or PD-L1, I think you saw in our release that we confirm the recent approval in Europe for a really interesting indication that could be very valuable for patients. And as Michael just said additionally to that with our own internal program, which is a PD-1 not a PD-L1 that's a PD-1 Sutimlimab.

In December, in fact we initiated the study that Mikael just mentioned. And I think the thing that we are very excited about in terms of its potential for Sutimlimab is that it's a subcutaneous PD-1, we think the marketplace for more convenient PD-1 is actually still to be developed plainly PD-1 given the efficacy data across the whole range of tumors have enormous potential to be a backbone for the long term. So we think that if that market evolves, the opportunity for a PD-1 that has effectiveness, which has been proven across in a multiple other campaigns, but also combining significant convenience enhancements is actually very significant. So we are very excited about sutimlimab and we will keep you updated with progress is that program developed.

A - Charles Triano {BIO 3844941 <GO>}

All right. Thanks, John. Next question please.

Operator

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

Q - Navin Jacob {BIO 20931208 <GO>}

Hi, thanks so much for taking the questions and squeezing me in here. But a couple of questions for Frank and one for Mikael, if I may. Frank, just wondering if there was any change in inventory in the US during between Q3, Q4 of 2021 and sorry, 2020 and how does that compare to the change in inventory in the US between Q3 and Q4 in 2019? And then separately, Frank, the high 20% margins so for the COVID vaccine, suggest at 100% economics closer to 50 to somewhere between 50% to 60% op margin but wondering because I know obviously you're investing a ton into R&D moving forward into 2022, could we, how much could we see that operating margin increase over time as R&D spend a lowers.

And then for Mikael, Mikael, obviously a key question that everyone has a durability of efficacy, which is in part affected by new variance but how exactly is the agency measuring durability of efficacy are requiring manufacturer is the developers to a measure durability of efficacy, what specific trials and or endpoints or how is that characterized please, any color would be helpful.

A - Albert Bourla {BIO 18495385 <GO>}

Frank?

A - Frank D'Amelio

So thanks for the questions, Navin. So, on the inventory, approximately three weeks on hand at roughly the same as it was last year at the end of the year. And in terms of Q3 to Q4, no major change in the rhythm of the inventory roughly it's approximately three weeks on hand. And then in terms of the high 20s percentage, it's interesting how you frame the question because the way I think about it is the R&D spend isn't the big is not the big driver of what's getting us to that high 20s which is kind of how I heard the question.

It's really the comps and it's, like I said because primarily it's the pandemic pricing and then the different layers of the I answered earlier on in the Q&A. That's really what's driving the gross -- the higher, the lower IBT as a percentage of margin. So I think you mentioned 50% based on all the current financials were lower, significantly lower than 50% on the gross margin. And then when you layer in the expenses beginning to the high 20s now, to your question beyond that, once again, I think the big factor in it will be the pricing will continue to take the unit costs down as volumes improve, the royalty is with the royalty is the profit share was the profit share is.

Obviously we're spending R&D, but we'll continue to manage the R&D spend to me the big-ticket item there will be, what we can do on pricing and that obviously the more volume we generate below will take the unit costs and those items will clearly dropped to the bottom line.

A - Charles Triano {BIO 3844941 <GO>}

Right. Thanks, Frank. And operator, if we could take our last question at this time.

Operator

Your final question comes from the line of Chris Schott from JP Morgan.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks so much for the question. Just two quick ones here. Maybe on the BCMA bispecific, can you just talk a little bit about how you see agents fitting in the treatment paradigm and maybe as importantly how you're seeing the competitive landscape shaping up so basically what differentiation do you see with your program versus others?

And maybe just then a follow-up on capital allocation priorities, post Upjohn share repo has the company has been historically pretty active on that front. Should we think about less or kind of less relevant role for share repo in the paradigm going forward I guess we think about maybe little bit higher dividend payout ratio. And then some of these priorities to bring in additional assets ahead of the '26 through, '28 LOE cycles, would love to kind of hear how you see that fitting in the mix. Thanks so much.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Sorry I was muted, Mikael. Would you like to take the first question?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, BCMA Elranatamab, we are very excited about that. And it had at the high dose 1,000 microgram per kilogram 83% response rate in a heavily pre-treated population and it has shown a significant number of stringent or complete responses and it's given us up to., it a very nice tolerability profile. So although it's with several infants. I think we have an opportunity to aim for being absolutely in the first wave here and with a really nice best-in-class profile, we are moving with the fast opportunity we see for accelerated approval in triple-refractory patients that either have seen no prior BVMA treatment or have seen prior BCMA treatments such as ADC your CAR-T so we are when such cohorts to start soon with potential for registration. And we are moving into second and third line in combination with classical, in it's and other company's that are used in order to come to first and second line opportunity, particularly with the (inaudible). Thank you very much.

A - Albert Bourla {BIO 18495385 <GO>}

And to increase as regards to the stock repurchases. We never say never to anything. Right. We don't want to have any weapons and I, we will say whenever, but clearly the salary purchases wholes at the bottom of the priorities right now. The dividend is a clear commitment to of course and we believe there are tremendous opportunities right now to invest in the business as front office, we have already an authorization from the Board, but it could take your size, is there any point to buy back shares and we could have been moment asked for renewal. But this is not very priority right now the priority, it is to make sure. But we keep investing for business development and infrastructure. So for example COVID, the franchise it will thrive over time and our R&D machine will get many more programs from the external world but can run through it. Thank you very much.

A - Charles Triano {BIO 3844941 <GO>}

Albert just add some closing remarks.

A - Albert Bourla {BIO 18495385 <GO>}

So thank you very much for joining us today and for your continued engagement with Pfizer. But when you Pfizer is all about two things science and basis. I think it's a combination of a bold decades long transformation from a diversified enterprise and more focused and innovative biopharma company. By uniting Transformational Technology and testing science we are pioneering biopharmaceutical innovations to do more than just difficult diseases. I think we are curing and preventing them.

We believe our success in development COVID-19 was just the beginning, thanks to the incredible transformation we have executed over the last 10 years. Pfizer is now advancing one of the strongest pipelines in our company's history. We have 95 potential new therapies or indications in six therapeutic areas with nine programs in registration 24 in Phase III clinical trials. This means 95 potential opportunities to change the lives of patients around the world. And when patients win we all win. Have a great rest of your day.

Operator

Ladies and gentlemen, this does conclude Pfizer's fourth quarter 2020 Earnings Conference Call. You may now disconnect.