Q1 2020 Earnings Call

Company Participants

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

Other Participants

- Andrew Baum, Analyst
- Carter Gould, Analyst
- Chris Schott, Analyst
- David Risinger, Analyst
- Louise Chen, Analyst
- Navin Jacob, Analyst
- Randall Stanicky, 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 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.

Chuck Triano {BIO 3844941 <GO>}

Thank you, operator. Good morning, everyone, and thanks for joining us today to review Pfizer's first quarter 2020 financial results, our reaffirmed full year 2020 financial

guidance, Pfizer's role in helping find solutions for the COVID-19 pandemic, as well as other relevant business topics. As usual, I'm joined today by our Chairman and CEO, Albert Bourla; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; Angela Hwang, Group President, Pfizer 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 will see here on this slide that covers our legal disclosures. 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. During my remarks, I will discuss the first quarter business performance as well as recent milestones from our pipeline. However, I want to start with a few thoughts about the COVID-19 pandemic and Pfizer's role in helping find solutions. It goes without saying that this is an extraordinary, difficult and unprecedented time for everyone. The public health challenges posed by COVID-19 have impacted almost every aspect of our lives. As one of the world's largest biopharmaceutical companies, our role in this crisis is dual. On the one hand, we are focused on maintaining the continuous supply of our medicines and vaccines to patients around the globe, while protecting the safety and well-being of all our colleagues, of course. On the other hand, we are working with experts, both within and outside Pfizer, to bring our expertise, capital and resources to help contribute potential medical solutions to this pandemic.

Let me share a few examples of what we are doing on this front. With the burden on hospitals happening around the globe and expected to increase, the continued supply of our medicines and vaccines is now more critical than ever. I'm pleased to say that the Pfizer Global Supply team has done an outstanding job keeping our manufacturing sites and the related distribution channels operational without significant supply disruptions.

In terms of finding medical solutions for the pandemic, we are collaborating with industry partners and academic institutions to develop potential novel approaches to prevent and treat COVID-19. We aim to leave no stone unturned and we have made advances on multiple fronts. Regarding prevention, we recently announced that Pfizer and a German biotech company BioNTech have entered into a global collaboration agreement to co-develop the potential first-in-class, mRNA-based coronavirus vaccine program aimed at preventing COVID-19 infection. Last week, we received the regulatory approval from German authority, PaulEhrlich-Institut to commence the first clinical trial for our COVID-19 vaccine candidates in Germany. And the first patient has already been dosed. We also plan to conduct trials in the US upon the regulatory approval, which is expected shortly. BioNTech and Pfizer will also work jointly to bring the vaccine to market worldwide, excluding China, which is already covered through a separate BioNTech collaboration, subject of course to successful development and regulatory approvals. We plan to manufacture millions of doses of the potential vaccine at-risk by the end of 2020 to

accelerate availability in the event the development program is successful and we obtain regulatory approval and then to rapidly scale up capacity to produce potentially hundreds of millions of doses in 2021. I want to thank everyone in both companies working on this project.

Regarding the potential treatment, we now know our lead molecule is a very potent inhibitor of the SARS-CoV-2 3C-like protease with confirmed antiviral activity against SARS-CoV-2. We accelerating towards the clinic and commencing regulatory discussions, while also undertaking additional antiviral testing and working on the formulation for IV administration. We invested in clinical materials over a month ago, ahead of understanding antiviral activity to accelerate the potential clinical study as early as August or September of this year. We also continue to provide our clinical and regulatory experience to small biotech companies working on promising COVID-19 therapies. And we have several Pfizer medicines that they are a subject of novel research projects for investigation in patients with COVID-19. I want to publicly thank all our R&D colleagues. We are working tirelessly and often late into the night to find potential vaccines and treatments that could bring an end to this pandemic. At the end, I'm confident that science will win the battle against COVID-19.

Now, let me turn to our results for the first quarter. Obviously, we experienced both headwinds and tailwinds related to COVID-19 during this quarter. On the one hand, our sales representatives in many regions were not able to detail with physicians in their offices. In addition, patient visits to doctor offices declined significantly beginning at the end of March, which is expected to negatively impact new diagnosis of conditions requiring physician-administered diagnostic tests beginning in the second quarter of 2020. On the other hand, we saw an uptick in our hospital business unit in the first quarter of 2020 due in large part to stronger than usual demand for some of anti -- of our anti-infective medicines, as well as other sterile injectable products utilized in the incubation and ongoing treatment of mechanically-ventilated COVID-19 patients. In total, we estimate that these puts and takes resulted in a net benefit of only 1% of -- to our first quarter 2020 Biopharma revenues, primarily reflecting increased demand for certain products in Pfizer's hospital portfolio and increasing the wholesale inventory levels for Eliquis. In the face of these factors, we delivered a strong quarterly performance overall, highlighted by 12% operational revenue growth in our Pfizer Biopharmaceuticals Group, which will be the business that remains following the anticipated closing of the Upjohn transaction in the second half of 2020.

We also saw total company revenue negatively impacted by three expected events. The July '19 loss of exclusivity in the US for Lyrica, the July 31st completion of the Consumer Healthcare joint venture transaction with GSK, which removed our recording of revenue and expenses from this business and declines from Lipitor and Norvasc in China due to the volume-based procurement program, which was initially implemented in March 2019 and expanded nationwide in December of 2019. The Lyrica and consumer impacts will both begin to annualize in the third quarter. The Biopharmaceutical Group's outstanding growth was again driven primarily by strong performances from our key growth drivers. These include Eliquis, Vyndaqel/Vyndamax, Ibrance, Inlyta and Xtandi as well as 15% operational growth in emerging markets. Our Oncology business was particularly strong, up 25% operationally compared with a year ago quarter. Global Ibrance revenues

increased 11% operationally to $1.2 billion during this quarter. In the US, Ibrance revenues grew 15% and it retained its strong leadership position in the CDK class due to increased volumes and continued CDK class market share gains. The international market delivered strong 25% volume growth in the quarter, led by emerging markets. These volume growth was offset by pricing pressures in the EU5 markets. As a result, operational revenue growth outside the US was 5%.

For Xtandi, alliance revenues in the US were up 25% for the quarter and when combined with our royalty income on ex-US sales totaled $256 million. Xtandi is the market leader with 38% market share in total prescriptions in advanced prostate cancer. Demand reached an all-time high during the quarter due to solid growth in castrate-resistant prostate cancer, expansion into metastatic castration-sensitive prostate cancer and overall novel hormone therapy class growth. We are pleased with the early impact of the launch of Xtandi for metastatic castration-sensitive prostate cancer in the US. Xtandi is the first and only oral treatment approved by the FDA in three distinct types of prostate cancer.

And related to our acquisition of Array BioPharma, we are pleased by the FDA's approval of the lead Array asset, Braftovi, in combination with cetuximab for the treatment of adult patients with metastatic colorectal cancer, with a BRAF mutation after prior therapy. We believe that Braftovi doublet has the potential to make a meaningful impact on the lives of those living with this disease.

Beyond Oncology, we had several other strong product performances. Eliquis continued to perform well. Pfizer shares of the global revenue was up 29% operationally to $1.3 billion. This growth was driven primarily by continued increased adoption in non-valvular atrial fibrillation, as well as oral anti-coagulant market share gains. Additionally, US growth was favorably impacted by COVID-19-related wholesaler buying patterns, partially offset by a lower net price.

Looking at our Rare Diseases business. Vyndaqel and Vyndamax continue to show strong US performance. Overall, these breakthrough medicines contributed $127 million in revenue in the US in the first quarter. Our disease awareness efforts helped drive the estimated diagnosis rate to 13% in the first quarter compared with only 1% to 2% prior to launch. At the end of the quarter, more than 13,000 patients have been diagnosed, more than 8,500 patients have received the prescription and more than 5,000 patients have received the drug. For the quarter, we estimate the average number of patients in the US taking Vyndaqel was approximately 4,600. These numbers include patients who are receiving the drug at no cost through our Patient Assistance programs. In Europe, we received approval of Vyndaqel for the treatment of ATTR-cardiomyopathy in February and we have already launched in two markets, including Germany. That said, as a result of stay at home orders, we are seeing a slowdown in new diagnosis in April, as fewer patients are visiting doctors' offices for consultations or scintigraphy tests.

Global Xeljanz revenue were up 8% operationally in the quarter to $451 million. The revenues outside the US were up 38% operationally, primarily reflecting continued uptake in rheumatoid arthritis, as well as from the recent launch of the ulcerative colitis indication in certain developed markets. In the US, Xeljanz's revenue were down 4%. This reflected continued strong demand across all approved indications more than offset by a lower net

price due to higher rebating from commercial contracts signed in 2019, as well as temporary lowering of wholesaler inventory levels in first quarter 2020. Wholesaler inventory levels for Xeljanz were restored to normal levels in early April 2020 during Pfizer's second quarter as underlying volume demand has remained consistently strong.

Global Prevnar 13 revenues were down 1% operationally to $1.45 billion with 11% operational growth internationally, primarily reflecting continued pediatric uptake in China and the overall favorable impact of timing associated with government purchases for the pediatric indication in certain emerging markets, including Russia and Turkey. In the US, revenues were down 10%, primarily reflecting the unfavorable impact of timing associated with government purchases for the pediatric indication compared with the previous year quarter.

Looking at our Sterile Injectables portfolio, our manufacturing recovery is having a positive impact on the top line in the US. We have completed most of our supply remediation and continue to invest in modernization necessary to sustain performance. In response to increasing demand due to the COVID-19 pandemic, in March, Pfizer shipped more than 30 critical medicines to -- at 150% of baseline demand from this portfolio and more than 10 of these exceeded 200%. In certain cases, Pfizer supported up to 600% of baseline demand. Of note, our global revenue from our Sterile Injectable portfolio grew 15% operationally in the first quarter and increased 6% sequentially compared to fourth quarter of 2019. Additionally, more than 90% of our Injectables portfolio is in stock today.

Our global Biosimilars portfolio grew 63% operationally to $288 million in the quarter. The increase was driven largely by steady growth in the US, thanks to a strong performance of RETACRIT and continued progress with Inflectra, which was up 46% due to increased demand in open-systems, partially offset by price erosion. We also have launched three therapeutic monoclonal antibody oncology biosimilars in the US over the past few months and we are encouraged by our initial engagements with payers and providers, where we have not seen the negative impact of exclusionary contracting by the innovator companies that we had seen with the Inflectra launch.

As expected for -- revenues for our Upjohn business were down 37% operationally in the quarter to $2 billion. The decline was primarily driven by the expected significant volume declines for Lyrica in the US due to multi-source generic competition that began in July 2019. Upjohn revenues in China declined 41% operationally, primarily driven by anticipated declines for Lipitor and Norvasc, primarily resulting from the value-based procurement program, which was initially implemented in March 2019 and expanded nationwide beginning in December of 2019. These declines were consistent with our previous guidance for the Upjohn business. Regarding Upjohn's combination with Mylan, the industrial logic continues to be very attractive. While we pushed all the expected timing of the deal close to the second half of 2020 mostly due to administrative delays related to COVID-19, there is no change in our commitment to the transaction and we continue to move forward with all pre-closing activities and initiatives. Last week, the European Commission approved the proposed transaction, subject to divestment of certain of Mylan's generic medicines.

Turning now to R&D, we continue to be excited with the progress we are making with our pipeline and the potential it has to deliver significant benefits to patients across a range of therapeutic areas. Since our last earnings call on January 28th, we have seen some exciting milestones. We announced top line results from a Phase 3 study of Pfizer's 20-valent pneumococcal conjugate vaccine in adults 18 years of age or older. The vaccine candidate demonstrated a safety and immunogenicity profile comparable to licensed pneumococcal vaccines and we expect to file the adult 20-valent pneumococcal indication with the FDA in early fourth quarter of 2020.

We are -- announced we are encouraged about our potential maternal RSV vaccine, which had a recent Phase 2 readout with preliminary positive data with favorable tolerability and safety. And Phase 3 start is projected within a few months and we look forward to discussing this data with regulators.

We announced positive top line results from a third Phase 3 trial of abrocitinib, a study which evaluated the safety and efficacy of abrocitinib in adults with moderate to severe atopic dermatitis, who were also on background topical therapy and included an active control arm treated with dupilumab plus background topical therapy met both of its co-primary efficacy endpoints. In the key secondary endpoint, the proportion of patients in the abrocitinib 200 milligram arm that achieved a clinically significant reduction in each, by week two was statistically superior to the dupilumab arm, while the 100 milligram abrocitinib arm was numerically higher, but not statistically significantly higher than the dupilumab arm at week two. These data along with the results from other positive monotherapy pivotal trials will support regulatory filings, starting with the FDA planned for later this year.

Our filing for tanezumab was accepted for review in March at both the FDA and EMA. We are pursuing approval for the 2.5 milligram dose administered subcutaneously in patients with chronic pain due to moderate to severe osteoarthritis who have failed prior analgesics. In the US, we expect an Advisory Committee meeting later this year and a decision from the FDA in December, a decision from the EU regulators is expected next year.

Our ACC/DGAT2 inhibitor combination has achieved positive results in the Phase 2 proof-of-concept study for NASH. Data from that study will be served at an upcoming Congress. The licensed ANGPTL3 antisense oligonucleotide project successfully concluded the Phase 1/2a part of the program, meeting its primary endpoint and multiple secondary endpoints. The program has advanced towards Phase 2b with a focus on two indications, severe hypertriglyceridemia and cardiovascular risk reduction.

Preliminary results in our Phase 1b Duchenne muscular dystrophy gene therapy study support the continuation of the trial and the start off a Phase 3 program, which is anticipated to begin dosing patients in the second half of 2020, subject to regulatory approvals, of course. The Phase 1b trial continues despite the current COVID-19 pandemic because of the urgent need of these patients and their families. We will be sharing more results from this trial on May 15th at the American Society for Gene and Cell Therapy Conference.

Despite a brief pause in clinical trial recruitment, most of our key pipeline programs continue to move forward. The anticipated timing for top line data from the Phase 3 Ibrance PALLAS study remains early 2021, for example, because the study was already fully enrolled before the pause. 20-valent pneumococcal adult studies also have completed and we're just waiting on the results. We look forward to rescheduling our Investor Day previously scheduled for March 31st once we have a clear picture of the evolving guidelines regarding COVID-19.

So now, before I turn it over to Frank, I would like to give you a broader view of our reaffirmed 2020 financial guidance for Total Pfizer. Pfizer and Upjohn combined, which I see as a strong message regarding the strength and resilience of our business. I will speak to Total Pfizer and Frank will provide more specifics in his comments. Since our initial 2020 guidance was provided in January, we have seen three incremental factors that we have incorporated into our guidance. R&D investments we have made and plan to make during 2020 to combat COVID-19, the projected COVID-19 impact and other operational impact items on our operations in terms of the P&L, and changes in foreign exchange rates.

In terms of the first factor, as you have seen us announce already, we see promising science-based opportunity in terms of combating COVID-19. In support of this highly important initiative, we are increasing our projected R&D investment for 2020 by $500 million. This predominantly reflects the investment in our COVID-19 vaccine development collaboration with BioNTech, which is rapidly moving forward.

Regarding the second factor, we have analyzed the changing dynamics within our markets and believe that we are likely to see more negative impacts during the second quarter, driven primarily by reductions in new patient starts due to reduced office visits and diagnostic testing and lower levels of elective surgeries, but we are modeling an overall economic recovery beginning in the second half of this year with an expectation that healthcare activity will approach pre-COVID-19 levels later in the year.

Obviously, there are still uncertainties, but we believe we do have a resilient business model and a clear line of sight for our business as compared with those in many other sectors of the economy. Our portfolio comprises medicines where we see potential different types of impact from the COVID-19 pandemic. Some are medically necessary such Eliquis and Ibrance, but also more reliant on continuing patients. Some are generally more reliant on new patient starts, such as Vyndaqel or Chantix or used in certain surgeries and still other medicines that have been identified as medically necessary in the pandemic such as some of our hospital sterile injectable products and are seeing increased utilization because of the COVID-19 crisis. Also remember that a large proportion of our portfolio is made up of oral or self-injective medicines and that do not require a visit to infusion center or doctor's office. In addition, a majority of revenue for our portfolio is derived from specialty pharmacy channels, which enables direct delivery of these medicines to patients. Both are positive factors in the current environment. Given that, we anticipated a blended impact of COVID-19.

Let me offer a few specifics regarding how we are projecting the COVID-19 pandemic to impact our larger revenue growth drivers. Medicines such as Ibrance and Eliquis both are

expected to continue to generate new patient starts, but they are also more mature and therefore more dependent on maintenance therapy with continuing patients. Both are oral medicines, leaders in their categories and very well known to physicians. Attributes such as Eliquis note its safety profile, which does not require regular monitoring, may provide an opportunity for appropriate patients with an alternative treatment option during this time. As for Ibrance, while we would expect to see some minimal impact in new patient starts for Ibrance in second quarter, we also expect to see a catch-up in the second half of the year.

Vyndaqel is a good example of a recently launched product, not only it's highly dependent on new patient starts, but the diagnosis process also requires a doctor's office visit and subsequent diagnostic testing through additional office visits. We anticipate a drop in new patient starts and are seeing that currently -- and we are seeing that currently, but we believe the strong momentum behind this program will resume in the second half of the year in terms of diagnosis, prescribing and patient access.

Regarding Prevnar, while we anticipate a temporary slowdown in vaccinations in the second quarter, we believe that a resurgence in infant vaccinations to catch up could take place in the second half of the year. And for adults, we anticipate there will be heightened awareness of the importance of getting vaccinated prior to the next flu season.

As of Xeljanz, in a category where many other products are infusions, Xeljanz provide an oral options for patients, which should be well suited to the current environment. Because Xeljanz has been in the market for more than eight years, a large proportion of its revenues is driven by continuing patients. It also has broad payer access and patient copay support. We expect to see temporary impact to new patient starts for Xeljanz in the second quarter, but again, we expect to see a recovery in the second half of the year.

Where we are seeing a more pronounced negative impact is with medicines that might not seem as obvious. Chantix for example, which is generally prescribed during a well visit with a physician. And BMP, which is used in elective surgeries would be two products I would highlight here in this category. So when looking across the portfolio, we don't see this as revenue that will be lost forever, but mainly as deferred revenue to be slowly recouped as the pandemic eases and we see a normalization of interactions between our sales force and physicians and between physicians and patients. As a result, we believe that the anticipated net impact of these factors in combination with some non-COVID-related operational improvements should be negligible in terms of our total company revenue rate projections for 2020. We have also reduced our SI&A guidance for the year. This reflects reduced spending on both direct and indirect SI&A during the first quarter, as well as some additional efficiencies identified for the remainder of 2020 in our indirect SI&A reduction initiatives. Lastly, regarding foreign exchange, since our initial guidance in January, the US dollar has strengthened, which drives an expected reduction of our revenues of approximately $600 million and negatively impacts adjusted earnings per share by approximately $0.04.

Bringing this all together now, our current view of the underlying strength, breadth and projected resilience of our business in this uncertain times allow us to absorb both incremental $500 million in projected R&D investment this year and the incrementally

negative foreign exchange impact to maintain our initial guidance ranges on both the top and bottom lines. In addition, I see the long-term fundamentals of our business remaining strong. And following the completion of the Upjohn transaction, I expect our business to be positioned to generate at least 6% compound annual revenue growth through 2025. We expect adjusted EPS obviously to grow even faster.

Now, I will turn it over to Frank. Frank?

Frank D'Amelio

Thanks, Albert. Good day, everyone. Before I walk you through our results for the quarter, I want to comment on the current global pandemic, which is impacting nearly every industry around the world. Despite the challenges inherent in operating in this environment, the fundamentals of our business continue to be strong and our outlook for the future of the company remains bright. We continue to have a strong balance sheet and favorable credit rating, which we expect to allow us to access the capital markets as needed, which was demonstrated in late March with the issuance of a $1.25 billion sustainability bond, the first of its kind in our industry. On the supply side, all 49 of our manufacturing facilities remain operational and we have not seen a significant disruption in our supply chain as a result of the pandemic.

To ensure the safety of our manufacturing colleagues while they perform this critical work, we have put in place enhanced safety measures at all of our plants, including investing in protective equipment, staggering shifts so that fewer colleagues are present at once, restricting site access to only essential workers and requiring colleagues to log their contacts while on site. I want to acknowledge how proud I am of the way our colleagues, many of whom are on the front lines in this fight, have responded to this crisis with courage and passion from those who are working around the clock on potential treatments or vaccines for COVID-19 to those who continue to operate our manufacturing and supply chains to ensure patients can have the medicines they need. It is in times like these that the strength of our culture and of our people really shines.

Now, on to the financials. First quarter 2020 revenues were $12 billion, down 7% operationally versus the year-ago quarter. Of course, most of this decline is due to the fact that we no longer report revenues for our Consumer Healthcare business. Excluding this impact, revenues were down 1% operationally. As Albert already explained in detail, our Biopharma revenues grew 12% operationally this quarter, driven by strength across multiple products with approximately 1 percentage point of that growth attributable to the net impact of COVID-19 on product sales. Upjohn revenues declined 37% operationally driven by generic competition for Lyrica in the US and declining sales of Lipitor and Norvasc in China due to the implementation and nationwide expansion of the volume-based procurement program. Importantly, both of these negative drivers were anticipated in our previous Upjohn guidance.

For total company, adjusted SI&A expenses in the quarter were down 16% operationally, approximately half of that decline was due to the fact that we no longer report expenses for the Consumer Healthcare business, the remainder of the decrease was driven by reductions in field force, advertising and promotional expenses due to the LOE of Lyrica

in the US and lower selling expenses for Lipitor and Norvasc in China due to volume-based procurement, as well as lower indirect SI&A spending associated with corporate enabling functions.

Both reported and adjusted diluted EPS for the first quarter were down compared to the year-ago quarter. The decrease was primarily due to lower revenues mainly driven by the loss of exclusivity for Lyrica in the US, partially offset by lower SI&A expenses. Finally, foreign exchange had a negative impact of $134 million or 1% on first quarter 2020 revenues and a $0.02 negative impact on adjusted diluted EPS compared to the year-ago quarter.

Before walking you through our guidance updates in detail, I want to acknowledge that no one currently knows exactly how and in what timeframe the COVID-19 pandemic will progress and eventually come to its resolution. Given those uncertainties, along with our desire to be as transparent as possible, we are providing on this chart the key COVID-19-related assumptions that are reflected in today's guidance update. In summary, our financial guidance reflects our expectation that most healthcare systems around the world will begin to resume their normal functions in the second half of 2020, including in-person doctor visits, new to brand prescription trends, sales force activities and clinical trial enrollment. The guidance also assumes we will be able to continue to operate our manufacturing and supply chain without material disruption and that we will continue to invest in potential treatments and vaccines against COVID-19 throughout 2020.

With that, let's take a look at our guidance. Consistent with last quarter, we are providing three sets of financial guidance. As a reminder, those three sets of guidance are as follows. Total company, which reflects our current construct of the Biopharma and Upjohn businesses and excludes any impact from the pending Upjohn combination with Mylan. Two, New Pfizer, which is a full year pro forma view that reflects the impact of the pending Viatris transaction by removing Upjohn and including $12 billion in cash proceeds from Upjohn to New Pfizer and other transaction-related factors such as transitional, service agreement revenue, and three, Upjohn as a standalone business. Let me remind you that the Upjohn guidance includes the Meridian business and our collaboration with Mylan in Japan as we discussed last quarter. All of these scenarios continue to be based a full year of revenues and expenses in 2020.

Beginning with total company, as Albert mentioned, we are reaffirming our guidance ranges for both revenue and adjusted diluted EPS despite absorbing incremental negative impacts due to foreign exchange fluctuations since mid-January of approximately $600 million on revenue and $0.04 on adjusted diluted EPS. Moving down the income statement, we lowered our cost of sales as a percentage of revenue guidance range by 0.4 percentage points to reflect favorability resulting from changes in product mix and other efficiencies. For selling information and administrative expenses, we are lowering our guidance range by $500 million. This reflects incremental cost savings opportunities, primarily related to indirect SI&A spending as well as actual and anticipated spending reductions as a result of the COVID-19 pandemic and as Albert already spoke about the $500 million upward revision to our R&D expense range. Finally, our guidance continues to anticipate no share repurchases in 2020.

Moving on to financial guidance for New Pfizer and Upjohn, despite absorbing negative incremental impacts on revenues due to changes in foreign exchange rates since mid-January of approximately $500 million for New Pfizer and $100 million for Upjohn, we are reaffirming the fiscal year 2020 revenue guidance ranges for both pro forma companies. Additionally, we are reaffirming the guidance ranges for adjusted IBT margin and adjusted diluted EPS for New Pfizer, as well as adjusted EBITDA for Upjohn. The only change to the guidance we gave for New Pfizer is a $1 billion reduction in the range for operating cash flow driven entirely by a $1.25 billion voluntary US pension contribution, which we plan to make in the second half of 2020.

Moving on to key takeaways. In the first quarter of 2020, our company performed well in a challenging environment driven by strong revenue growth from our Biopharma business. We reaffirmed our 2020 guidance for revenues and adjusted diluted EPS and we achieved multiple product and pipeline milestones since our last quarterly update, some of which are listed here demonstrating the continued advancement of our late-stage pipeline. Finally, we paid $2.1 billion in dividends to our shareholders this quarter. As always, we remain committed to delivering attractive shareholder returns in 2020 and beyond.

Now, I'll turn it back to Chuck.

Chuck Triano {BIO 3844941 <GO>}

Thanks Frank and thanks Albert for those comments. Operator, can we please now poll for questions?

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>}

Yes, thanks very much for the detailed review and congratulations on the performance. So, I had two questions, please. First is with respect to the guidance and the second is on the vaccine candidate. So, with respect to the guidance and the assumptions on slide 13, could you just discuss what you're assuming with respect to a potential resurgence in COVID during the start of the flu season in the fourth quarter and the impact of that on healthcare systems and physician visits? And then second, with respect to your vaccine candidate with BioNtech, could you just discuss your level of conviction that you have the right candidate that will be safe and effective? And when do you expect to generate animal data and when do you expect to generate initial human data? Thank you very much.

A - Albert Bourla {BIO 18495385 <GO>}

Dave, thank you very much. Very good questions as usual. The first one with guidance, let me ask Frank to make comments about the assumptions.

A - Frank D'Amelio

So, David, on our guidance, we are assuming a recovery in the second half of the year. We expect the second quarter to be the quarter that's primarily impacted in a negative way from the COVID-19 virus, but we do expect a recovery in the second half of the year and that includes the items that we talked about in our comments, in-person doctor visits start up again, new to brand prescription trends, sales force activities, clinical trial enrollment and obviously all of our sites continuing to operate and provide medicines to patients the way that they're currently doing today. So punchline, second half recovery and the healthcare system returns to normal operations.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Frank. And now, Mikael, I think you would like to comment on the vaccine. Before let me say just one thing on the vaccine drugs. This is a new technology, but we are very familiar with both the technology and the company because we are working with them the last two years in a joint project to develop, with the same technology, a flu vaccine. So we jump into the COVID-19 when they need to merge jointly together and we are applying of course all the learnings of the -- learnings that we've had with the technology during the last two years.

Now, Mikael, can you speak -- please speak more specifics about the -- this specific project?

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you, Albert and Dave for asking this important question. I would start by saying I think we have the most comprehensive SARS-CoV-2 vaccine program currently ongoing and it's specifically related to mRNA. As Albert alluded to, we had built a lot of experience on the various type of mRNA and the formulation of lipid nanoparticles through two years' work on flu and a lot of different animal data coming from our work and work from BioNTech on both oncology and other programs. When it comes to the specific light speed program as it's called that has basically in two to three months moved from the drawing table to dosing patients right now, it contains, as we have announced, four different vaccine candidates that will be started in humans, the first one already dosed, and that allow us more than anyone to cherry-pick from a new disease like COV-19 what mRNA type, what antigen is the most effective and allow us to pick one or two to move into pivotal studies. So that covers unmodified mRNA, modified and self-amplifying. To the best of my knowledge, we are the only one currently having self-amplified mRNA in the clinic, which would allow you to dose at lower dose than any other construct. We already have animal data from rodents on the various constructs that are encouraging and we also have data from patients here that shows that the two antigen that we picked seems to be the most relevant for intervening and utilizing viruses. And by having picked two spike or the smaller component receptor binding domain, again, I think we will be able to cherry-pick what turns out to translate most effectively in man. So more animal data will come over the next few weeks on primates and I expect human data to come late May, June from the first experiments performed on plasma from vaccinated patient and

this is a unique trial design with continuous data flow that should allow us to progress fast, share data with regulators. So we expect the flow of data coming May, June and then move into expanded trials that could allow emergency use or accelerated approval coming in the fall, possibly October and onwards. So thank you very much for your question.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Mikael. And also let me add here what -- the reason also why we jumped into advice [ph]. It's not only because we had the familiarity with the company, with the technology and we have discussed this project that was very exciting, but also we have -- we are uniquely positioned to help during this crisis because we have the end-to-end capabilities. We are having very strong capabilities from early pre-clinical results all the way to manufacturing. And frankly, as we have, I think, said, but I'll make it very clear now also. We are planning to manufacture at risk this vaccine. So if the technical success and regulatory approvals are there, we will have doses available in -- during the last quarter of this year. And also, it would be an omission if I wouldn't mention right now that how grateful we are with the advice and collaboration that FDA is giving us that they are trying to work their timelines day and night as well, so that they can help bring to the world a solution. Thank you very much. Let's go to the next question, Chuck.

A - Chuck Triano {BIO 3844941 <GO>}

Yeah. Next question. Thank you.

Operator

Your next question comes from the line of Chris Schott from JPMorgan.

Q - Chris Schott {BIO 6299911 <GO>}

Just two. First on Vyndaqel and the impact from COVID. It sounds like you're expecting a slowdown in diagnosis rates in the quarter, should we also expect that Rxs and patients receiving drug should also slow or could those actually keep ramping once you've identified a product they can keep working through the process? My second question on Vyndaqel was also on payer mix. You've had a little bit more experience with the product and we're still trying to get a sense of where gross to net could shake out for the product. So any additional statistics here in terms of how many patients are getting free drug, how many are reimbursed, just any data there would be very helpful? My final question was on Prevnar in infants. Are your expectations for that product for the year unchanged, so that we're going to obviously see get 2Q impact, but you get kind of a catch-up in the second half of the year or should we actually be thinking about Prevnar infant expectations for the year coming down as that catch-up won't offset the lost sales in the quarter? Thanks so much.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Schott. I think all three questions are very well suited for Angela to answer. So, Angela, why don't you start with Vyndaqel?

A - Angela Hwang {BIO 20415694 <GO>}

Great, thank you. Thanks for those questions, Chris. So firstly on Vyndaqel, as you can see, we continue to have just great momentum behind this product and we do believe that this will sustain its performance throughout the year. As Albert mentioned, we do think that there will be some slowdown in NRxs in the second quarter. And actually just to align with those comments, we did see that in our patient hub enrollments, and since the middle of March, we saw a decline of about 20% in the last four weeks compared to the previous four weeks. So I think that this comment about new patient starts is one that we are seeing in the patient hub. However, let's also think about the great attributes of Vyndaqel. It's an oral medication. It's one that is being delivered through specialty pharmacy directly to patients' homes and it's one that because of its mortality benefits decreases hospitalizations, all of these really play well to the time that we're in right now in this pandemic. And so we anticipate our continuing patients to be able to continue on their drug and be able to stay on therapy. So no impact on TRxs.

Your second question was around the payer mix. And on that front, we have not seen a change in terms of the numbers of patients on commercial, this is Medicare versus other books of business. That has been pretty consistent through the time from launch and our Medicare patients are the predominant part of our patient population and that hasn't changed at all.

And then I think your third question was on Prevnar Ps [ph]. And on Prevnar Ps, similarly consistent with comments made earlier. We do anticipate second quarter to have some slowdown and this is just because, while business aren't taking place, there is a lot more caution regarding visits to pediatricians' offices, so we do anticipate some slowdown there, but we also know both from our own research and from our representatives that pediatricians are anxious and are motivated to get the well visits back and to have our infants as well as our children vaccinated. And therefore based on that and based on the fact that we expect a recovery in second half per Frank's comments about our assumptions, we do anticipate a catch-up towards the second half of the year that will allow us to attain our expectations that we had for Ps for all of 2020.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Angela.

A - Chuck Triano {BIO 3844941 <GO>}

Thanks, Angela. Operator, next question, please.

Operator

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

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my question. I hope you all are staying safe. Mikael, on your antiviral for COVID, you're going down the protease inhibitor track instead of the nuc. Maybe if you could explain the thought process and if you could also lay out for us the

exact EC50s that you're seeing with your 3CL inhibitor? And I ask because some of the initial 3CL inhibitor constructs you had chosen against SARS, their EC50s were above 10. So I wonder, if you are seeing something closer to a 1 on the protease inhibitor you've chosen? And secondly, on COVID vaccine, Mikael, I'm curious, what's the exact threshold on utilizing antibody tighter that you want to see for you to say, you know what, we have something?

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Umer. So Mikael, the space is yours.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you very much, Umer. Great questions here.

So let's start with the protease inhibitors. We had a privileged -- this isn't just re-purposed protease inhibitor for a -- from a distant relative, we had a collection of compounds that showed very potent activity to the SARS-CoV-1 and we were able to model and show that its very strong similarity in the binding and have confirmed that these compounds on the SARS-CoV-2, the COVID-19 disease are very potent. We are talking about very potent nanomolar type of binding and this is supported by X-ray data available that shows again unique, highly selective binding patterns. We are now doing cellular antiviral studies, which initial data is encouraging again showing potent activity which needs to be studied on different cell types, where the virus may be harbored. Altogether, we think these are very promising drug candidates and we are moving swiftly ahead with scaling up, adding other IND type of data to potentially pending regulatory dialogues that have initiated able to dose patients around August this year.

We're also working on oral follow-on drugs and have identified several candidates that show suitability for this type of delivery system. So all together, I feel very encouraged that this could be the first-in-class protease drug for SARS-CoV-2 and we'll keep you posted as we advance. On the vaccine, clearly we are looking at what could be animal data guiding us on what should be the relevant thresholds in order to have neutralization of virus and we have in discussion with regulators gotten good feedback on data from multiple animal models that we are pursuing that could help to possibly even create a surrogate endpoint. We're also looking at convalescent serum from patients to understand which of those that are used for treatment intervention guides us and we will actually use those also in intervention models. So while we expect in our Phase 2 study later summer, Q3 early, to generate human data on our vaccine when it comes to impact on events, these will be supplemented by multiple animal models and plasma levels of neutralizing antibodies used in transfusion therapies. So all-in-all, a multi-pronged approach to nail down the type of levels we should be aiming for and to keep with the most aspirational goal of getting a vaccine that can be considered for emergency use accelerated approval around Q3 this year. Thank you very much.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Mikael. And also to add that with the antiviral as we did with the vaccines, we are producing at-risk clinical material. So in case we decide to go in the summer into

clinical studies, as Mikael said, we will be able to do it immediately. Great. Chuck, to the next question.

A - Chuck Triano {BIO 3844941 <GO>}

Yes. Next question, please?

Operator

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

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the questions. Maybe two for me. The first is, given the current environment, I was just wondering if there are any changes to how you're approaching capital allocation here? Do you expect M&A and business development opportunities to increase? I think you had talked on your fourth quarter call about potentially finalizing some deals in the first half of the year. So just wondering, if there's been any change on that front? And then my second question is on your 20-valent pneumococcal disease program. We've now seen the top line data for the adult Phase 3 setting come out. Just wondering, what outstanding questions are left to you on that program as you look ahead on the forward and securing the filing in the fourth quarter? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much. Frank, would you like to make some comments on the capital allocation?

A - Frank D'Amelio

Sure. So Terence on capital allocation, our priorities remain the same, which are obviously dividends and we paid a $2.1 billion dividend to our shareholders this quarter, investing in the business and then obviously M&A, so mergers and acquisitions. And clearly, there has been some value reset in the industry and you can see some of that with some of the biotechs and obviously as we always do, we'll look for opportunities where we think it's a good deal for our company and for our shareholders. The one thing I want to balance this with though is even though valuations reset, Board of Directors and management teams' expectations don't necessarily reset at the same pace. So that's always something we have to work our way through. But from a high-level priority perspective, our capital allocation priorities remain the same.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Frank. And then, Mikael, is there anything that we are waiting more on pneumococcal adult or are -- you think you can file?

A - Mikael Dolsten {BIO 16368411 <GO>}

We are very confident in the pneumococcal adult after a completion of the main efficacy study that we have done a press release and it has the immunogenicity, safety and

tolerability that we were looking for. We also recently had a lot consistency study to readout, which again showed similar grade profile for the 20-valent to be used in the adult setting. We are still having one study that is for patients previously immunized with a pneumococcal vaccine that will be coming shortly. But for naive patients, we do have all data available looking like a very strong profile and weighing just to supplement with the dataset coming on previously immunized, which -- this would be to expand the coverage and that's why we feel very confident about filing. And you heard from Albert's introduction that we've moved it to early Q4. Thank you very much.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you.

A - Chuck Triano {BIO 3844941 <GO>}

That's great. Operator, can we go to the next question, please?

Operator

Your next question comes from the line of Randall Stanicky from RBC Capital Markets.

Q - Randall Stanicky {BIO 6967011 <GO>}

Great, thanks guys. Just two questions probably both for Angela. Can you just talk about the Ibrance trends, particularly the EU5 price headwinds? When did those update and how should we think about Ibrance growth for this year? And then just a follow-up on Vyndaqel. The 13% diagnosis rate, it's a nice jump from 4Q of 9%. Any change to where you guys think that can ultimately get to putting aside near-term headwinds from COVID? Thanks.

A - Albert Bourla {BIO 18495385 <GO>}

Angela, go ahead.

A - Angela Hwang {BIO 20415694 <GO>}

Sure. So on Ibrance in the EU, I want to affirm that our fundamentals and our growth for Ibrance in the EU continues to be really strong. And we continue to see great growth opportunities into the future. Right now, the first-line metastatic breast cancer share of the CDK class is only at 38, so there is room for growth here and we do have a strong leading market share of 68% of all CDKs. So I think just right there, you can see that there are continued opportunities for growth and that is how we see it.

We saw very strong double-digit growth for Ibrance in volume. And what you didn't see and why that didn't translate into net sales is because we negotiated a number of very large contracts with certain large European countries. Many of these happened in Q4 of 2019. And because these contracts are multi-year, what you get here now is some stability in that and so this has allowed us to re-base our business. And so those impacts are already included in our guidance. And because of the timing of when these contracts were signed, we expect to return to net sales growth in the second half of 2020. So all-in-

all, I think it's just the timing and the year-on-year comparison that is driving the effect of what you're seeing from a net sales perspective, but I want to reaffirm that our fundamentals are strong, the value proposition of Ibrance is strong and we continue to see tremendous growth opportunities both for the class as well as our own share.

Your next question was about Vyndaqel, and I think your question was around just sort of diagnosis and whether we're seeing anything particular there. And no. I mean, the strategies that we have deployed from the beginning, which is to find a heightened awareness around which patients we should suspect for ATTR-CM and then have those patients be then diagnosed through scintigraphy continues to be the mainstay of how we are generating diagnosis. With time, we are deploying and we're experimenting with our artificial intelligence and different sort of predictive models that might allow us to again support the suspicion of these patients, but I would say that our strategies have been rather consistent since launch and I think that the diagnosis rates that we're seeing tell us that what we've been doing is working well. There is great receptivity for this product, both from physicians as well as from patients. We are very active on the education front both from a diagnosis and from a treatment perspective. So, I think that what we've been doing has -- is really working well and we'll continue to do so.

A - Chuck Triano {BIO 3844941 <GO>}

Great, thanks for the detail, Angela. Our next question, please, operator.

Operator

Your next question comes from Tim Anderson from Wolfe Research.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. On your 20-valent pneumococcal conjugate vaccine, just an update on timing for when we are likely to see the Phase 3 trial start in Ps to keep that gap with Merck as small as possible? And then second question on adjuvant Ibrance. Just an update on timing of when we will see the data and when you do top line that, are you likely to disclose any results or is it just going to be a qualitative top line? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Yes, thank you very much. Let me take quickly the adjuvant and then Mikael please answer the 20-valent and add if you have anything on the adjuvant. We have not run any interim analysis yet on PALLAS study and we expect, as we said before, the study will come to conclusion. Actually, it will come to completion, which means that we'll not stop to expect during the interim because we have set very high criteria for stopping. So typically, we do not announce when we have interim analysis data and visibility, unless if we stop. So as I said, we don't have data, we haven't performed an analysis yet, an analysis hasn't has been performed. Typically, we don't announce it and the study will come to completion as expected early in 2021. So Mikael, on the 20-valent -- on the Ps when we can start the Phase 3 and if you have to add something on the PALLAS?

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you very much Albert and Tim for the questions. We -- after that press release of the three injections immunization of the PED [ph], we later shared that the fourth dose further substantiate the data. We have had extensive regulatory dialogues in the US and elsewhere and shared all those datasets. So we are planning to start the PED, PCV20 very soon. We're talking likely about just a few weeks to be clear. So that's our projected plans right now. And I think you said very well on the adjuvant Ibrance studies that we feel very optimistic and good about them and just waiting for them to report on the date that we have communicated.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you. Angela, do you want to add anything on the pediatric marketplace as we see it potentially playing out?

A - Angela Hwang {BIO 20415694 <GO>}

Sure, Chuck. So as we said, we will launch tentatively after the Merck 15. However, we don't anticipate that the ACIP will make a preferential recommendation between the two. And therefore, we believe that PCV13 will compete with PCV15 until the PCV20 comes to market. And we are confident of our PCV13, it has tremendous experience with healthcare professionals, we have a very strong account management developed through our -- with our customers through the years that we've been on the market and we also have a very reliable supply track record. And so despite the -- there may be gap in launches, we anticipate to be competing in the market and to continue to support the benefits of PCV13 to infants.

A - Chuck Triano {BIO 3844941 <GO>}

Great, thank you. Operator, can we please move to the next question?

Operator

Your next question is from Louise Chen from Cantor.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my questions here. So my first question for you is, do you have any update or more details on the go-forward strategy for Pfizer post the Upjohn separation? As it pertains to M&A pipeline assets, what you're thinking about there? And then what in your DMD Phase 1b data gave you confidence to move into Phase 3 studies? Where are you with manufacturing and what type of data do you think you will report out at ASGCT? And then my last question here is just back on PCV20. Just curious, if you think from the adult side that the ACIP recommendation would change at all if you were to get approved for PCV20? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Let me maybe speak a little bit on the strategy on M&A and then John also can add to that. And then I will ask Mikael on the DMD. And then maybe Angela on the PCV20, again, how ACIP will do the adults.

On the go-forward strategy, our side is very clear and will remain the same. Post the expected separation with Upjohn, Pfizer will become a top line best-in-class growth story. And we are feeling more and more confident about it. We are strengthening our language around the 6%. Today, I said at least 6% we will grow and that we expect that will continue. Now, the M&A is not a strategy, it is a tool to support the strategy. And that's why the M&A in the past were much more geared towards buying revenues or buying earnings growth by big mergers that could cut cost because this is what we needed at that time. Right now moving forward, we are not in a need to buy EPS. Our EPS will grow organically as our revenues will grow organically. So our M&A, although we never say never on anything on M&A, right now it is -- we will continue that -- our strategy is not to go to a big M&A for the following three reasons. One, it is that very few targets will provide -- will not dilute our growth, very few. Most of them will grow less than us, so we'll have dilution. Secondly that targets usually they want a significant premium and those makes me feel that most of the values captured by the shareholders of the acquirer, like the one that is making the acquisition and, of course, those big acquisitions are creating some distractions, which R&D could be an issue. So these are the considerations.

In terms of saying where are we going to invest our capital if this is not our first priority for the reasons that I said, we are going to invest in early Phase 2, Phase 3 ready-to-start potential medicines that could be part of our pipeline, so that we will strengthen the pipeline that is coming post -- as products post '25, '26, '27, '28, so that we can sustain the growth that already we feel very confident we have organically or in the next five, six years. So that's on our strategy and M&A. Now, DMD, Mikael, what makes you optimistic?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you very much. I mean, it's such a transformative area treating these boys with Duchenne. So we have now treated as you will learn more at the conference 11 patients, eight of them at the high dose of 3e to the 14 and we continue to show -- see very consistent data on efficacy looking at the dystrophin expression, the distribution of the dystrophin. And as we have treated more patients and the early boys that were treated, we have now longer observation period, we can also see that durability seems to exceed 12 months when it comes to the gene expression, which makes us feeling very good that this could be a long durability for these boys and we also have data coming out on muscle health, creatine kinase and more recently MRI that allow us again to add another level of confidence that we are changing the health of the muscles. And finally for the motor function, well, you use clinical scales, we have seen now across a number of treated boys a favorable data on the Northstar Index. And I want to point out that we have seen it across different ages, because if you mainly monitor early boys for this, they do have some spontaneous improvement that could be difficult to differ from treatment in use, but we have also seen it on older boys, where you expect decline, but we have noted improvement instead. So all-in-all, we feel that we have now accumulated a very robust dataset on efficacy and we have learnt important experiences how to mitigate risk and manage any possible safety event. Of course, we have one of the largest effort on new therapy manufacturing that has been expanding in North Carolina and that will all come together now in our plans to start Phase 3 trials in just a few months. So thank you for your interest.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Mikael. Really, a very exciting news for these boys, particularly that they have virtually no solutions right now. Angela, what about our views on what could be the recommendations of ACIP on the adult pneumococcal vaccine, the PCV20 and competition?

A - Angela Hwang {BIO 20415694 <GO>}

Yes. So we're really excited about our PCV20 program and specifically about the breadth that of serotype coverage that PCV20 provides and we really see the benefit in two ways. One, first of all, these incremental stereotypes are associated with high case totality rates, antibiotic resistance and/or meningitis. So these are sort of serious diseases that these serotypes will be able to cover. But also relative to PCV15, PCV20 is expected to provide 33% more coverage against IPD strains in adults. So with these data, our plan is to bring this forward to the CDC, anti-regulatory authority, we will certainly be discussing recommendations and what all this means, but I think in the end, we all know that this is a decision that the CDC needs to make and we will be having these conversations with them as our program develops. But certainly, we feel very strongly about the potential benefits and the additional coverage that PCV20 can provide. And we'll keep you posted with what happens with the CDC. Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Angela. And John, do you have to add any comments on our go-forward strategy, given that you are managing this area very successfully right now and particularly on M&A targets or licensing targets that we have?

A - John Young {BIO 17639257 <GO>}

Thanks, Albert, and thanks for the question. Obviously, we don't talk about specific targets as you all know, but I think Albert sort of really hit on the sort of main points in our -- in his answer, which is we feel really good about the prospects for the continued growth of our core business. In terms of business development to strengthen that, our focus is absolutely on clinical stage assets. I think Frank touched on this in his answer to capital allocation earlier on, but we're really very focused on clinical stage assets that could complement our existing internal pipeline that we feel good about. So we're going to be focused on areas including oncology, where there could be interesting tuck-ins. We're going to be looking at rare disease. There's a lot of innovation taking place there and I think we're uniquely placed because of the capabilities and manufacturing and development that Mikael has touched on to add to our pipeline. And we continue to look across our other areas as well as select opportunities. So we think there are opportunities out there. We are -- continue to be very active in this space, but, of course, we're always going to make sure that we are disciplined. We deploy capital in a way that really optimizes value for our shareholders, but most importantly for our patients. So I think between Albert's and Frank's answers, hopefully that gives you a flavor of how we feel about capital deployment and business development for our business strategy post the separation of Upjohn.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much. And I'm not sure if we answered also the question on DMD about manufacturing. And yes, we feel very good about manufacturing. Our investments are progressing very nicely and we will be able to manufacture at scale for the DMD, provided that it's successful and ready. So Chuck, please go to the next question.

A - Chuck Triano {BIO 3844941 <GO>}

Yes. Please, let's move to the next, operator.

Operator

Your next question comes from Steve Scala from Cowen.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. I have a few questions. First on abrocitinib, I believe only the higher dose was better than Dupixent, but there were safety issues at that dose and it was not superior on itch. It seems the outlook is not all that positive. You obviously think differently. So could you explain? Secondly, you spoke about the PALLAS trial. But to clarify the PENELOPE-B neoadjuvant trial, did you say the readout is now Q1 of '21? We had thought it was likely to be top line this year. And then lastly, can you just quantify the Eliquis stocking in the quarter? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much. I will very quickly answer the PENELOPE. No, the PENELOPE is expected to come in the second half of this year. The PALLAS is expected to come early next year. This is exactly as we have said it before. Mikael, why do you -- are you excited about abrocitinib?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. We are very excited about abrocitinib. And let me just punctuate a few things. In the JADE COMPARE study, we show that both high and medium doses met co-primary endpoint in very effectively reducing eczema. We had a key secondary endpoint of comparing itch to Dupixent's standard-of-care and this is one of the most patient-centric endpoint impacting quality of life both day and night time. And the high dose statistically significantly showed better effects clinically meaningful than Dupixent, while the lower dose, the 100 milligram numerically was better, but didn't reach statistical significance. Overall, what we see is more rapid onset with our oral abrocitinib than the biological depiction. And we see a more rapid onset numerically whether you look at skin clearance or whether you see -- look at itch. And while there is some more infections always with higher doses of JAK inhibitors, we think and I believe that the benefit versus the risk is still very favorable. These are mild to moderate cases, most attenuate and basically all attenuate if you discontinue treatment. And I want to finally emphasize that we have a very exciting additional trial that is not necessary for filing, but it's coming later this year, the trial regimen, that will study if you start on the 200 milligram, which we know will clear skin, reduce itch much faster than standard-of-care and then you can switch maintenance to the 100 milligram, which likely have a lower level of any adverse event, including infection. So that give you potentially max flexibility to treat and clean up itch and skin and

go on a lower dose. But again, the benefit risk to me looks very favorable also for the higher dose. These infections are relatively rare, they're mild to moderate and can easily be managed and are quite common for patients treated by dermatologists. So I feel very good about high dose being superior and the lower dose being somewhat similar to Dupixent, still having faster onset of action numerically and is oral and very convenient to take. I hope that gave you a good sense why I feel encouraged to see these new treatment options for patients moving to regulatory discussions and hopefully soon available. Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Mikael. And Angela, what about the inventory levels, can you explain of Eliquis?

A - Angela Hwang {BIO 20415694 <GO>}

Yes. In terms of just Eliquis impact, what we saw was an uptick in terms of inventory levels to prepare for the pandemic and the impact was about in the mid single-digits in terms of worldwide revenue.

A - Chuck Triano {BIO 3844941 <GO>}

Great, thank you. We have time for a couple more questions, operator. Can we move to the next one?

Operator

Your next question comes from the line of Andrew Baum from Citi.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. I know that you've added a couple of very distinguished scientists to Board, you've also added the former FDA commissioner under your tenure, Albert, as well as the Mylan transaction. Should we think about this has been accelerated evolution of Pfizer in terms of trying to improve the ROI that has had historically on R&D? And if so, aside from the measures that you outlined, perhaps you could highlight any other internal, either organizational or talent enrichment that's gone on that also points in that direction?

And then second to Mike. Pfizer seems to have pivoted away from immuno-oncology as many others have done, given the disappointments post PD1. If we do see the emergence of novel IO targets such as TIGIT and there's some others out there with randomized Phase 2 trials, should I assume that Pfizer's willing to reengage back in that field? And I know I'm exaggerating in terms of binary, but it does seem that you have pivoted back towards more molecules? And then finally if you could comment on the anticipated treatment duration in the real world setting for PALLAS, given the issues with adverse events as well as reimbursement friction for Medicare patients?

A - Albert Bourla {BIO 18495385 <GO>}

Yeah. Andrew, can you repeat the first part of your question, the ROI?

Q - Andrew Baum {BIO 1540495 <GO>}

Yeah. So I was basically saying that under your tenure Albert, there is a notable addition of three individuals with high scientific calibers. So, obviously, the former FDA commissioner, but also two very distinguished scientists, as well as decomplexifying the organization by the Upjohn transaction. So when I think about the evolution of the business under Pfizer, it does seem that the concerted attempt to try and shine more light or improve the ROI through some of these measures. So I was asking, are there any other internal measures, talent enrichment inside the organization or new R&D structures designed to improve R&D either through accelerating programs, killing early, the normal stuff, but is something changed in the profile of improving the ROI in R&D, particularly --?

A - Albert Bourla {BIO 18495385 <GO>}

I got it now. No, thank you very much. Thank you very much. And the answer is absolutely yes. It is not by chance that right now in our Board, we have five top scientists, four of them physicians, top scientists that they have unique expertise either in regulatory science, they have unique expertise in development, they have unique expertise in basic science both in primary care and metabolic diseases and immunology. We have also through Susan Hockfield -- she was the pioneer of bringing together the genomics data with computation power and she was the first biologist and first woman to be a head of -- president of the MIT. And this is a very clear statement, but Pfizer is different. Pfizer is a science-based company and this is where the growth is coming. And we are adding those two Board members to provide also more visibility, but also because they help us with their very high knowledge. Now, there is not one or two, there are multiple measures that -- metrics that we are using to assess if indeed our R&D machine is a new machine and if we can count on it in this new strategy and they are all pointing in this direction. I think we've made very clear that Pfizer of the past, because you asked a question how -- if you can kill quickly and if you can, let's say, progress things that they really matter rather than move everything. Pfizer of the past had a success rate of Phase 2 studies of 15%. When I say of the past, few years back, 15% when the industry was a third [ph]. Today, Pfizer's success rate, it is close to 50%, 5-0, and that's on a rolling four years' assessment right now. And I'm sure next year, we'll be 50% -- rolling 50%. And this is not the only one. In 2018, we were the company that introduced most new molecular entities of anybody else who would expect apart from Pfizer and we can go on and on. John Young has a very detailed list of criteria and he is monitoring the governing process that is making sure that as we allocate capital, we allocate with R&D ROI in mind. And also I will add that the speed with which the company is reacting has nothing to do with the company of the past. And by the way, this is very well indicated in the way that we were able to move better than any biotech in speeding developing vaccine or in the speeding developing an antiviral. And the reason why we have been able to accomplish this speed in addition to be cultural, it is also that we have break the company into five distinct business units, plus one -- six, excuse me, six, together with hospitals, business units. And that each one of these business units, for example, oncology, vaccines, rare diseases, they operate like a biotech. They make decisions end-to-end from commercial to early R&D within this structure, like if I said, if they were a biotech company and they are presenting their requests for finance and -- into the committee that John Young is managing, so that we can allocate the capital. And last but not least, although Pfizer is laser-focused on this and ROE of R&D as we are progressing, it was absolutely to avoid misunderstanding, it was absolutely non -- of -- it was absolutely not one of our criteria when we jumped into the

COVID-19 programs. The only criteria that we used as we jumped into the COVID-19 projects was if we are -- we can have a solution, if we can make the difference, if we think that our technology is good one, so that we can bring a vaccine or an antiviral because this is not times that ROIs will prevail for COVID-19, it is times that solutions will be found. So with that, I hope I gave you some color on how Pfizer is changing and what is the meaning which is more than symbolic of appointing the new Board members. And I go to Mikael to answer your second question.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, thank you for that question. We think one needs to be careful and not throw everything under the kitchen sink into immuno-oncology. So we try really to cherry-pick the areas where we have learnt after the initial positioning of PDxs. One example is bifunctional antibodies. We have a dose escalation of a BCMA bifunctional that looks very encouraging with subdued unique profile. We have follow-on PD1 bifunctional with cytokines that can boost immune resistance and we have oncolytic viruses. We were successful combining Inlyta with PDx and we're building on that experience to now move from actually our Boulder unit former Array a small molecule this year that we think is an immune enhancer for cancer an XLMR [ph] inhibitor. So I hope you got that answer that we are cherry-picking the areas where we think we can break resistance to IO rather than just throwing everything on to this area.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much for your questions, Andrew. So, Chuck?

A - Chuck Triano {BIO 3844941 <GO>}

Yes. Let's try to get a couple more in. Operator, next question, please.

Operator

Your next question is from Vamil Divan from Mizuho Securities.

Q - Vamil Divan {BIO 15748296 <GO>}

Great, thanks for taking my question. So one maybe following up on the abrocitinib question from before, Steve's question for Mikael, I definitely get the enthusiasm you have on the efficacy side and the convenience side. I guess, my question is just more on safety, now that you've seen the COMPARE data and as we think about the filing, just your level of confidence on the label being clean from some of the black box warnings we see for the current JAKs and tumor infections malignancies, but obviously also BTEs. I think in talking to dermatologists, it feels like it will be critical for it to be -- to not have a black box in order to compete with a product like Dupixent. So maybe just you can share your views there. And then second one also on the immunology pipeline. Your JAK3, the 1600, just curious on timing of that. I think clinical trial says that the trial is expected to read out the Phase 2, Phase 3 expected in September of this year, but it also said that's still recruiting patients. So just trying to get a better sense of when we might see data for that product, I know it has breakthrough status. Thanks.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Thank you, Vamil. Mikael, jump immediately.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Abrocitinib, we have a large database. I feel very good about its profile. We have not seen any cardiovascular issues. And that's really what is worrying about safety, while we see as expected some viral skin infections, I consider them more of safety, tolerability and very mild and moderate and can be well managed with standard experience in medical practice. I cannot speculate about black box, that's really for regulators. Our JAK3 in alopecia has a very unique profile. The most selective of all JAK that I have seen this far, I -- we think readout will be probably as we have predicted mid-'21 and this is a pivotal study that could go quickly to filing. We do have end of this year a number of JAK inhibitor readouts in the Phase 2, like JAK3 in vitiligo, we have oral TYK2 in psoriasis and topical in atopic dermatitis. So we will keep you busy with the flow of news. Thank you.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you, Mikael. Operator, can we get another question, please?

Operator

Your next question is from Navin Jacob from UBS.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi, thanks so much. Navin from UBS. Thanks for fitting me in. Mikael just wanted to just touch upon the commentary with regards to the regulators allowing surrogate markers for the SARS-CoV-2 vaccine. Just want to dig into that a little bit more. What specifically will they be looking for that allows speedy approval? And then I want to understand the manufacturing targets that you have by year-end, if approved. If approved, I just want to understand, is it -- I'm assuming it's going to be under a sort of expanded access use basis for healthcare workers. And then what do you need from regulators for a broad approval for the general public, any kind of clarity around that would be helpful?

A - Albert Bourla {BIO 18495385 <GO>}

Yeah. I do not know how the regulators would like to regulate that, so -- and I leave it to them. But I can answer the question on the manufacturing. So we expect that we will have in the last quarter of this year millions of doses basically ready. And then for '21, we could ramp up to hundreds of millions of doses available. Now, Mikael may be a little bit you can answer the question about the endpoints or the surrogate endpoints.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. No, there are of course interests, both regulators and farmers, to see how we can learn maximally to allow potentially very important vaccine quickly to deal with this both medical and business crisis. So we have had ample discussions with the highest level of regulatory leaders in both US and Europe. So on the surrogate side or a two-animal guiding principle, if you can show for life threatening diseases data and we are pursuing

mice/hamsters as well as primate studies that are ongoing and will hopefully show to us what level of immune activity interferes with the virus. And we're also doing some I think really creative studies taking patient sera and testing them how they can intervene in these models and trying to correlate convalescent patient transfusions and what levels protect the disease or can halt the progression of disease in patients. So I think this is a unique area, where we will have human and animal data coming together in Q3 to possibly provide a surrogate, but we are planning from our Phase 2 study of the vaccines to also have human event rates. So it's more of having a really comprehensive approach to bring confidence and accelerate the potential approval or emergency use of this. It's not relying on just one approach, it's multiple approaches that we're bringing together in close dialogues with the highest level of regulators.

A - Chuck Triano {BIO 3844941 <GO>}

Great. Thank you, Mikael. Operator, we have time for one more question. So if we can move to our last question, please?

Operator

Your final question comes from the line of Carter Gould from Barclays.

Q - Carter Gould {BIO 21330584 <GO>}

Great, thanks. Thanks for fitting me in. I guess just one on sort of your view on the O-US pricing dynamics coming out of COVID. Just your expectations on the potential likelihood of incremental pricing pressure from government-funded healthcare systems, given likely pressure on EU budgets and is it your expectation we see similar austerity measures like we saw last decade? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Yeah. So I think it's very difficult to predict. In any case, I think our assumptions it is that pricing is not a growth driver, pricing is -- volume is going to be our growth driver, even without COVID. But I think if I have to speak on high level on COVID right now, I think -- and not on the short-term, but on the long-term as you were asking, I see two dynamics here. One is the one that you mentioned, which is likely governments will have, let's say, budgetary pressures and we know that that's typically an area that they try to go. So that I think will be towards the negatives. But also we see that the value proposition of the pharmaceutical industry has been drastically reset in the minds of the people right now because the pharmaceutical industry right now in the middle of this crisis represent the hope of the billions of people and the hundreds of millions of enterprises that we will find a solution towards that. And I think that will work on the very positive sign. So remains to be seen what will be the net-net of those two areas, but I believe that in any case, it's not going to drive growth by pricing, it's going to be by volume.

So I guess this is the end of -- and thank you very much for this question, really appreciate it. So I think this is the end, Chuck, so let me just thank you all for joining us today, for your continued interest and engagement within Pfizer. We are very happy to provide information and also we're very happy to relay it to you. As I said at the start, this is an extremely difficult time for everyone. As such, it is both a great privilege and a great

responsibility for our colleagues to serve patients at this moment. We have an opportunity to demonstrate the power of our science and we will do everything we can to do to be a part of the solution to this problem. And I want to close by acknowledging the healthcare workers on the front lines whose heroic efforts have been an inspiration to all of us. Their courage, their dedication and expertise have saved countless lives right now and probably in the future even more. And on behalf of whole Pfizer colleagues and their families, I say thank you. So have a great rest of your day.

Operator

Ladies and gentlemen, this does conclude Pfizer's first quarter 2020 earnings conference call. You may now disconnect.
