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EDITED TRANSCRIPT

PFE - Q1 2020 Pfizer Inc Earnings Call

EVENT DATE/TIME: APRIL 28, 2020 / 2:00PM GMT

OVERVIEW:

Co. reported 1Q20 revenues of \$12b.



APRIL 28, 2020 / 2:00PM, PFE - Q1 2020 Pfizer Inc Earnings Call

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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.

Charles E. Triano - Pfizer Inc. - SVP of IR

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](https://www.pfizer.com/investors). You'll 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?



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Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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 continued 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 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 the German biotech company, BioNTech, has entered into a global collaboration agreement to codevelop the potential first-in-class mRNA-based coronavirus vaccine program aimed at preventing COVID-19 infection. Last week, we received regulatory approval from German authority Paul-Ehrlich-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 U.S. upon regulatory approval, which is expected to start. 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 a 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 are 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 the subject of novel research projects for investigation in patients with COVID-19. I want to publicly thank all our R&D colleagues who 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 the first quarter of 2020 due in large part to stronger-than-usual demand for some of our anti-infective medicines as well as other sterile injectable products utilized in the intubation and ongoing treatment of mechanically ventilated COVID-19 patients.



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In total, we estimate that these puts and takes resulted in a net benefit of only 1% to our first quarter 2020 Biopharma revenues primarily reflecting increased demand for certain products in Pfizer's Hospital portfolio and an increase in wholesaler 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 3 expected events: the July 19 loss of exclusivity in the U.S. for Lyrica; the July 31 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, VYNDALCEL, 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 the year ago quarter. Global IBRANCE revenues increased 11% operationally to \$1.2 billion during this quarter. In the U.S., 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. This volume growth was offset by pricing pressures in the EU5 markets. As a result, operational revenue growth outside the U.S. was 5%. For XTANDI, alliance revenues in the U.S. were up 25% for the quarter, and when combined with our royalty income on ex U.S. 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 U.S. XTANDI is the first and only oral treatment approved by the FDA in 3 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, BRAFOTOVI, in combination with cetuximab for the treatment of adult patients with metastatic colorectal cancer with a BRAF mutation after prior therapy. We believe that BRAFOTOVI 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 sales of the global revenue was up 29% operationally to \$1.3 billion. This growth was driven primarily by continued increased adoption in nonvalvular atrial fibrillation as well as oral anticoagulant market share gains. Additionally, U.S. growth was favorably impacted by COVID-19-related wholesaler buying patterns, partially offset by a lower net price.

Looking at our Rare Diseases business, VYNDALCEL and VYNDAMAX continue to show strong U.S. performance. Overall, these breakthrough medicines contributed \$127 million in revenue in the U.S. 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 30,000 patients have been diagnosed, more than 8,500 patients have received a prescription and more than 5,000 patients have received the drug. For the quarter, we estimate the average number of patients in the U.S. taking VYNDALCEL 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 VYNDALCEL for the treatment of ATTR cardiomyopathy in February, and we have already launched in 2 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 doctor's offices for consultations or scintigraphy tests.

Global Xeljanz revenue were up 8% operationally in the quarter to \$451 million. Revenues outside the U.S. 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.



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In the U.S., Xeljanz revenues 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 U.S., 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 U.S. 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 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 U.S., 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 3 therapeutic monoclonal antibody oncology biosimilars in the U.S. 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 U.S. due to multi-share 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 volume-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 out 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 continued 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 28, 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. A 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. The 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 end points.



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In a key secondary end point, the proportion of patients in the abrocitinib 200-milligram arm that achieved a clinically significant reduction in each by week 2 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 2. These data, along with the results from other positive monotherapy clinical 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 U.S., 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 a Phase 2 proof-of-concept study for NASH. Data from that study will be shared at an upcoming congress. The license ANGPTL3 antisense oligonucleotide project successfully concluded the Phase 1/2a part of the program, meeting its primary end point and multiple secondary end points. The program has advanced towards Phase 2b with a focus on 2 indications: severe hyperglycemia 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 of 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 15 at the American Society for Gene & 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 are just waiting on the results. We look forward to rescheduling our Investor Day previously scheduled for March 31 once we have a clearer picture of the evolving guidelines regarding COVID-19.

So now before I turn it over to Frank, I would like to give you a broad review of our reaffirmed 2020 financial guidance for total Pfizer, Pfizer and Upjohn combined, which I see as a strong message regarding the strength and resiliency 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 3 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 health care 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 clearer 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 as 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.



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Also remember that a large proportion of our portfolio is made up of oral or self-injected medicines and that do not require a visit to an 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' noted safety profile, which does not require a 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 that not only is 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 product 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 would 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 for Xeljanz, in a category where many other products are infusions, Xeljanz provide an oral option for patients, which should be well suited to the current environment. Because Xeljanz has been in the market for more than 8 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 recovery in the second half of the year.

Where we are seeing a more pronounced negative impact is with medicines that may 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 2 products I would highlight here in this category. So when looking across the portfolio, we don't see these 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 U.S. dollar has strengthened, which drives an expected reduction on our revenues of approximately \$600 million and negatively impact 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 these 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?



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Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

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 a 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 U.S. 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 U.S. 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 U.S., 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 time frame 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 health care 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 3 sets of financial guidance. As a reminder, those 3 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

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Viatis 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,] (added by company after the call) Upjohn as a stand-alone 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 on 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] (added by company after the call). This reflects incremental cost savings opportunities primarily related to indirect S&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 U.S. 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.

Charles E. Triano - Pfizer Inc. - SVP of IR

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.

David Reed Risinger - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Yes. Thanks very much for the detailed review and congratulations on the performance. So I have 2 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 health care systems and physician visits?

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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?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

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 health care system returns to normal operations.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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 that 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 2 years in a joint project to develop with the same technology of flu vaccine.

So we jumped into the COVID-19 when the need emerged jointly together. And we are applying, of course, all the learnings of the -- the learnings that we had with the technology during the last few years. Now Mikael, can you please speak more specifics about this specific project?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

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 types of mRNA and the formulation of lipid nanoparticles through 2 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 2 to 3 months, moved from the drawing table to dosing patients right now, it contains, as we have announced, 4 different vaccine candidates that will be studied in humans, the first one already dosed, and that allow us, more than anyone, to cherry pick from a new disease like COVID-19 what mRNA type, what antigen is the most effective and allow us to pick 1 or 2 to move into pivotal studies. So that covers unmodified mRNA, modified and the self-amplifying. To the best of my knowledge, we're 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 patient sero that shows that the 2 antigen that we picked seems to be the most relevant for intervening and neutralizing viruses. And by having picked 2, 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 patients. And this is a unique trial design with continuous dataflow that should allow us to progress fast our 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 questions.



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Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Mikael. And also, let me add here that the reason also why we jumped into this is not only because we had the familiarity with the company, with the technology and we could discuss 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 preclinical research, all the way to manufacturing. And frankly, as we have, I think, said, but I 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 time lines day and night as well so that they can help bring to the world a solution.

Operator

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

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Just 2. First on VYNDALCEL and the impact from COVID. It sounds like you're expecting a slowdown in diagnosis rates in the quarter. Should we also expect that Rx's and patients receiving drugs 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 VYNDALCEL 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 a 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?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you. So I think all 3 questions are very well-suited for Angela to answer. So Angela, why don't you start with VYNDALCEL?

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Great. Thank you. Thanks for those questions, Chris. So firstly on VYNDALCEL, 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 NRx's in the second quarter. And actually, just to align with those comments, we did see that in our patient hub enrollment, the -- since the middle of March, we saw a decline of about 20% in the last 4 weeks compared to the previous 4 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 VYNDALCEL. It's an oral medication. It's one that is being delivered through the specialty pharmacy directly to patients' homes. 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 drugs and be able to stay on therapy, so no impact on TRx's.



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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 versus 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 the Prevnar peds. And on the Prevnar peds, similarly consistent with comments made earlier, we do anticipate second quarter to have some slowdown. And this is just because well visits 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 the 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 peds for all of 2020.

Operator

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

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

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 EC50 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 neutralizing antibody titer that you want to see for you to say, you know what, we have something.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. Thank you very much, Umer. Great questions here. So let's start with the protease inhibitors. We had a privilege that this isn't just a re-purposed protease inhibitor for -- from a distant relative. We had a collection of compounds that showed very potent activities through the SARS-CoV-1, and we were able to model and show that it's a 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 non-amiloride 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 initially, the data is encouraging again, showing potent activity which needs to be studied on different cell types where the virus may be harbored.

All together, we think we saw very promising drug candidates and we're moving swiftly ahead with scaling up, adding other IND type of data to potentially, pending regulatory dialogues that have initiated, be 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 end point. We are also looking at convalescence 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 impacts on events, this will be supplemented by multiple animal models and plasma levels of neutralizing antibodies used in transfusion therapies.



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So all in all, a multipronged 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.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Mikael. And also to add, just with the antiviral as we did with the vaccine, we are producing at-risk clinical material. So in case we decide to go in the summer into clinical studies, as Mikael said, we would be able to do it immediately.

Operator

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

Terence C. Flynn - Goldman Sachs Group Inc., Research Division - MD

Maybe 2 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 here on that program as you look ahead on the forward and securing the filing in the fourth quarter.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

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, some mergers and acquisitions. And clearly, there's 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.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

We are very confident in the pneumococcal adult after the completion of the main efficacy studies 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 of consistency studies to read out, which again showed similar grade profiles 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

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and weighing just to supplement with the dataset coming on the previously immunized, which this would be to expand their coverage, and that's why we feel very confident about filing. And you heard from Albert's introduction that we moved into early Q4. Thank you very much.

Operator

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

Randall S. Stanicky - *RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst*

Just 2 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?

Albert Bourla - *Pfizer Inc. - Chairman of the Board & CEO*

Angela, go ahead.

Angela Hwang - *Pfizer Inc. - Group President of Biopharmaceuticals Group*

Sure. So IBRANCE in the EU, I want to affirm that fundamentals and outgrowth 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's 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 multiyear, 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 strategy that we have deployed from the beginning, which is to find and heighten 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's 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 is really working well and will continue to do so.

Operator

Your next question comes from Tim Anderson from Wolfe Research.



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Timothy Minton Anderson - Wolfe Research, LLC - MD of Equity Research

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 peds to keep that gap with Merck as small as possible. And then a second question on adjuvant IBRANCE. Just an update on timing of when we will see the data. And when you do top line net, are you likely to disclose any results, or is it just going to get qualitative top line?

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Yes. Thank you very much. Let me take quickly the adjuvant, and then with Mikael, please answer the 20-valent and add if you have anything on the adjuvant. We have not run any interim analysis yet on the PALLAS study. And we expect, as we said before, what the study will come to conclusion -- actually, will come to completion, which means that we'll not stop, we 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. If an analysis 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 peds, when we can start the Phase 3 and if you have to add something on the PALACE.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Thank you very much, Albert and Tim, for the questions. We -- after the press release of the 3 injections, immunization of the peds, we later shared that the fourth dose further substantiate the data. We have had extensive regulatory dialogues in the U.S. 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.

Charles E. Triano - Pfizer Inc. - SVP of IR

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

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Sure, Chuck. So as you said, we will launch tentatively after the Merck 15. However, we don't anticipate that the ACIP will make a preferential recommendation between the 2. And therefore, we believe that PCV13 will compete with 15 until the PCV20 comes to market. And we are confident of our PCV13. It has tremendous experience with health care professionals. We have very strong account management developed through our -- with our customers through the year that we've been on the market, and we also have a very reliable supply track record. And so despite the, maybe, gap in launches, we anticipate to be competing in the market and to continue to support the benefits of PCV13 to infants.

Operator

Your next question is from Louise Chen from Cantor.

Louise Alesandra Chen - Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD

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'll 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.

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Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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 and around the 6%. Today, I said at least 6% will grow. And -- but 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 costs 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 in M&A, right now, it is -- will continue, that our strategy is not to go to a big M&A for the following 3 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 make me feel that most of the value is 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 then 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 in the next 5, 6 years. So that's on our strategy and M&A. Now DMD, Mikael, what makes you optimistic?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. 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, 8 of them at the high dose of 3E to the 14. And we continue to 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 unit 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, creatin kinase and more recently, MRI, that allow us again to add another level of confidence that we're changing the health of the muscles.

And finally, for the motor function, where you use clinical scales, we have seen now across a number of treated boys a favorable data on their 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 learned 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.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Mikael. You really have very exciting news for these boys, particularly as 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 20, and competition?

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Yes. So we're really excited about our PCV20 program and specifically about the breadth, that serotype coverage that PCV20 provides. And we really see the benefit in 2 ways. One, first of all, these incremental serotypes are associated with high-case fatality rates, antibiotic resistance and/or



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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 and our regulatory authorities. 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.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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?

John D. Young - Pfizer Inc. - Group President & Chief Business Officer

Hi. 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 point 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 in 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 continue to be very active in this space. But of course, we're always going to make sure that we are disciplined and 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.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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 is successful as well. So Chuck, let's go to the next question.

Operator

Your next question comes from Steve Scala from Cowen.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

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?



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Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. 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 end points in very effectively reducing eczema. We had a key secondary end point of comparing each to Dupixent's standard of care. And this is one of the most patient-centric end point impacting quality of life, both day and nighttime. And the high dose, statistically significantly showed better effect 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 Dupixent. And we see more rapid onset numerically, whether you look at skin clearance or whether you see -- look at itch. And what -- 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 is 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 will likely have a lower level of any adverse event, including infection. So that gives you potentially max flexibility to treat and clean up itch on 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 are 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 low 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.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Yes. In terms of this 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.

Charles E. Triano - Pfizer Inc. - SVP of IR

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.

Andrew Simon Baum - Citigroup Inc, Research Division - Global Head of Healthcare Research and MD

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



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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 PD-1. If we do see the emergence of novel IO targets such as to hit the SMOs out there for the randomized Phase 2 trials, should I assume that Pfizer is willing to reengage back in that field? So I know I'm exaggerating in terms of binary but it does seem that you have pivoted back towards small 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.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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

Andrew Simon Baum - Citigroup Inc, Research Division - Global Head of Healthcare Research and MD

Yes. So I was basically saying that under your tenure, Albert, there's a notable addition of 3 individuals with high scientific calibers. So obviously, the former FDA commissioner, but also 2 very distinguished scientists as well as de-complexifying the organization by the Upjohn transaction. So when I think about the evolution of the business under Pfizer, it does seem there's a concerted attempt to try and shine more light or improve the ROIs 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 has something changed in the profile of improving the ROI on R&D, particularly in the...

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

I got it now. No, thank you very much, thank you very much. And the answer is absolutely yes. It's not by chance, but right now, in our Board, we have 5 top scientists, 4 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. She was the first biologist and first woman to be any head of -- President of the MIT.

And this is a very clear statement that Pfizer is different. Pfizer is a science-based company, and this is where the growth is coming. And we are adding those Board members to provide also more visibility, but also because they help us with their very high knowledge. Now there is not 1 or 2. 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 the Pfizer of the past, because you ask a question of 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 the success rate of Phase 2 studies of 15%, what I saw in the past, a few years back, 15%, when the industry was 1/3.

Today, Pfizer's success rate, it is close to 50%, 5-0, and that's on a rolling 4 years assessment right now. And I'm sure, next year, we'll be 50% or rolling 50%. And this is not the only one. In 2019, we were the company that introduced most new molecular entities of anybody else who would expect that from Pfizer, and I can go on and on. John Young has a very detailed list of criteria and he is managing 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 speed in developing vaccine or in the speed in 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 can break the company into 5 distinct business units plus 1, 6 -- excuse me, 6, together with Hospital, business units, and that each one of these business units, for example, Oncology, Vaccines, Rare Disease, 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 request for finance and into the committee that John Young is managing so that you can allocate the capital.



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And last but not least, although Pfizer is laser-focused on this and ROI of R&D as we are progressing, it was absolutely to avoid misunderstanding. It was absolutely none 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 a good one so that we can bring a vaccine or an antiviral. Because this is not times that ROI should prevail for COVID-19, it is times that a solution should be found. So with that, I hope I gave you some color on how Pfizer is standing 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.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. 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 learned 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 subQ profile. We have follow-on PD-1 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 units from Array, a small molecule this year that we think is an immune enhancer for cancer, an AXL-MER 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 onto these areas.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

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

Charles E. Triano - Pfizer Inc. - SVP of IR

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.

Vamil Kishore Divan - Mizuho Securities USA LLC, Research Division - MD

Great. So one, maybe following up on the abrocitinib question from before, Steve's question, so 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 you 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 JAK and some infections and malignancies 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 if 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's expected to read out the Phase 2, Phase 3, expected in September of this year, but it also said that it'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.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Thank you, Vamil. Mikael, jump in.



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Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. 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 [mild] (corrected by company after the call) skin infections, I consider that more of safety tolerability and are 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've seen this far. 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'll keep you busy with a flow of news. Thank you.

Operator

Your next question is from Navin Jacob from UBS.

Navin Cyriac Jacob - UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic

Navin from UBS. Mikael, I just wanted to just touch upon the commentary with regards to the regulators allowing surrogate markers for the SARS-CoV-2 vaccine. I just want to dig into that a little bit more. What specifically will they be looking for that allows a 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 health care 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.

Albert Bourla - Pfizer Inc. - Chairman of the Board & CEO

Yes. 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, maybe a little bit you can answer the question about the end points or the surrogate end points.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. I know there are, of course, interest of both regulators and pharmas 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 U.S. and Europe. So on the surrogate side, there are 2 animal guiding principles, 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.

Charles E. Triano - Pfizer Inc. - SVP of IR

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

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Operator

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

Carter Lewis Gould - *Barclays Bank PLC, Research Division - Senior Analyst*

I guess just one on sort of your view on the OUS pricing dynamics coming out of COVID, just your expectations on the potential likelihood of incremental pricing pressure from government-funded health care systems given likely pressure on EU budgets. And is the expectation we see similar austerity measures like we saw last decade?

Albert Bourla - *Pfizer Inc. - Chairman of the Board & CEO*

Yes. So I think it's very difficult to predict. And 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 had to speak on a high level on COVID right now, I think -- and not on the short term but on the long term, as you are asking, I see 2 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 grow. So that, I think, will be towards the negative.

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 side. So it remains to be seen what will be the net-net of those 2 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. I 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 the information and are sure are very happy to relay 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 part of the solution to this problem.

And I want to close by acknowledging the health care 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 all 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.

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infringement(s) have not been finally resolved by the courts (i.e., an “at-risk launch”); success of clinical trials and Mylan’s, the Upjohn Business’s or the combined company’s ability to execute on new product opportunities; any changes in or difficulties with Mylan’s, the Upjohn Business’s or the combined company’s manufacturing facilities, including with respect to remediation and restructuring activities, supply chain or inventory or the ability to meet anticipated demand; the scope, timing and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on Mylan’s, the Upjohn Business’s or the combined company’s consolidated financial condition, results of operations and/or cash flows; Mylan’s, the Upjohn Business’s and the combined company’s ability to protect their respective intellectual property and preserve their respective intellectual property rights; the effect of any changes in customer and supplier relationships and customer purchasing patterns; the ability to attract and retain key personnel; changes in third-party relationships; actions and decisions of healthcare and pharmaceutical regulators; the impacts of competition; changes in the economic and financial conditions of the Upjohn Business or the business of Mylan or the combined company; the impact of outbreaks, epidemics or pandemics, such as the coronavirus pandemic; uncertainties regarding future demand, pricing and reimbursement for Mylan’s, the Upjohn Business’s or the combined company’s products; and uncertainties and matters beyond the control of management and other factors described under “Risk Factors” in each of Pfizer’s and Mylan’s Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission (“SEC”). These risks, as well as other risks associated with Mylan, the Upjohn Business, the combined company and the proposed transaction are also more fully discussed in the Registration Statement on Form S-4, as amended, which includes a proxy statement/prospectus (as amended, the “Form S-4”), which was filed by Newco with the SEC on October 25, 2019 and declared effective by the SEC on February 13, 2020, the Registration Statement on Form 10, as amended, which includes an information statement (as amended, the “Form 10”), which has been filed by Newco with the SEC on January 21, 2020 and amended on February 6, 2020 and subsequently withdrawn on March 11, 2020, and is expected to be refiled prior to its effectiveness, a definitive proxy statement, which was filed by Mylan with the SEC on February 13, 2020 (the “Proxy Statement”), and the prospectus, which was filed by Newco with the SEC on February 13, 2020 (the “Prospectus”). You can access Pfizer’s, Mylan’s and Newco’s filings with the SEC through the SEC website at www.sec.gov or through Pfizer’s or Mylan’s website, as applicable, and Pfizer and Mylan strongly encourage you to do so. Except as required by applicable law, Pfizer, Mylan and Newco undertake no obligation to update any statements herein for revisions or changes after this communication is made.

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