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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's Fourth Quarter 2022 Earnings Conference Call. Today's call is being recorded. At this time, I would like to turn the call over to Mr. Chris Stevo, Senior Vice President and Chief Investor Relations Officer. Please go ahead, sir.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thank you, Chelsea. Good morning. Welcome to Pfizer's fourth quarter earnings call. I'm joined today by Dr. Albert Bourla, our Chairman and CEO; Dave Denton, our CFO; and Dr. Mikael Dolsten, President of Worldwide Research and Development and Medical. Joining for the Q&A session, we

also have Angela Hwang, Chief Commercial Officer and President, Global Biopharmaceuticals Business; Aamir Malik, our Chief Business Innovation Officer; Dr. William Pao, our Chief Development Officer; and Doug Lankler, our General Counsel.

Before we begin the call, I want to remind you of some logistical items. The materials for this call and other earnings-related materials are on the Investor Relations section of Pfizer.com. Please see our forward-looking statements disclaimer on Slide 3 and additional information regarding these statements and our non-GAAP financial measures is available in our earnings release as well as in our SEC Forms 10-K and 10-Q under Risk Factors and Forward-Looking Information and Factors that May Affect Future Results.

Forward-looking statements on the call are subject to substantial risks and uncertainties, speak only as of the call's original date, and we undertake no obligation to update or revise any of the statements.

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

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

Thank you, Chris. Hello, everyone, and thank you for joining us today. During this morning's call, I will touch on some of our highlights from 2022 and share some thoughts regarding Pfizer's exciting near- and long-term growth plans. 2022 was an outstanding year for Pfizer on multiple fronts. We exceeded \$100 billion in revenues for the first time in our 174-year history. We maintained our industry-leading clinical success rates and further improved our cycle times, which were already among the industry's best. We were named to 10 different best employer lists, including those published by Forbes, LinkedIn, Glassdoor and others. And most important, more than 1.3 billion patients around the world were treated with our medicines and vaccines, a truly humbling achievement.

Our key growth drivers for the full year 2022 included global sales of PAXLOVID, strong growth of COMIRNATY in developed markets, the launch of Prevnar 20 for the adult population in the U.S., the continued strong growth of Eliquis globally, the strength of our VYNDAREL family globally and the addition of newly acquired products, Nurtec ODT, VYDURA and Oxbryta. Looking ahead, we foresee strong operational growth of 7% to 9% in 2023, excluding revenues from our COVID-19 products and the impact of foreign exchange. We expect our potential new launches, newly acquired products and in-line products with all -- will all contribute to this growth.

These projections include our forecast for several important potential product launches, including our RSV vaccine for older adults, potential Prevnar 20 pediatric indication and products and candidates that came to us through recent business development activities, including etrasimod for ulcerative colitis, Nurtec and zavegepant for migraine and Oxbryta for sickle cell disease. We are in the midst of an 18-month period during which we expect to have up to an unprecedented 19 new products or indications in the market. 15 of these 19 are from our internal pipeline, with the remaining 4 coming to Pfizer, as just explained, via the recent business development deals.

Recognizing the importance of these potential launches as well as those expected in 2024 to both Pfizer and the patients who rely on our innovations, we are increasing the support we are putting behind them by investing an incremental \$1.3 billion in SI&A expenses in 2023. Dave will provide more details on these investments during the presentation.

One example of a product that is already benefiting from this additional support is CIBINQO, which recently has seen an improving growth trajectory that we expect to continue through the course of 2023. In the fourth quarter of 2022, CIBINQO's new-to-brand prescriptions grew 84% sequentially, the fastest growth rate in the class. We have started 2023 with 55% commercial formulary access, and we expect that access to continue to improve during the year, especially with the upcoming expected expansion of the U.S. indication to include adolescents 12 to 18 years old, if approved.

We also introduced a new direct-to-consumer campaign in November, which has increased patient awareness of CIBINQO and led to more patients asking their doctors about it. We look forward to the expected U.S. launches of etrasimod in ulcerative colitis and ritlecitinib in alopecia areata, if approved, as well as the expected launch of ABRILADA, our biosimilar to Humira to further expand our franchise in immunology this year.

However, we recognize that investors are not only interested to hear this year's guidance, but also to understand the long-term growth prospects of the company. Particular questions are focused on our plans to offset the expected \$17 billion impact of the LOEs between 2025 and 2030 and our long-term projections for our COVID-19 products. We will try to address both, starting with this slide regarding our business, excluding COVID.

As you can see in this chart, we expect the 15 of the 19 potential launches that are coming from our internal pipeline to generate 2030 revenues that will more than offset the expected LOE losses forecast for '25 to 2030. The potential \$20 billion in this chart is a risk-adjusted number. I would also point out that some of the potential launches are expected to be bigger contributors to our growth than others. And if all 15 were to achieve their full potential, this figure could go even higher.

In addition, we believe we have the ability, if successful, to add at least \$25 billion of risk-adjusted revenues to our 2030 top line expectations through business development activity. As we have said previously, we believe the deals we have already done for Arena, Biohaven, Global Blood Therapeutics and ReViral have the potential to get us more than 40% of the way there with approximately \$10.5 billion in expected 2030 revenues. I am very pleased to see that the analysts' consensus expectations for the same revenues have already reached \$9.5 billion, closing materially the gap that previously existed between internal and external expectations.

Four of these products have already launched or are expected to launch, subject to regulatory approval in 2023. We also have more than enough capital to invest in the additional opportunities needed to meet or exceed this target. And of course, we have many more potential vaccines and medicines in our pipeline, with numerous launches expected in the '24 to 2030 time frame, if successful in clinical trials and approved. Some of the most promising assets include our oral GLP-1 candidate for diabetes and obesity. All of them are under this dotted box, XB. Potential combo vaccines for flu, COVID-19 and RSV; our potential vaccines for Lyme disease and shingles; multiple new oncology product candidates, including ARV-471 and our CDK4 inhibitor for endocrine receptor-positive breast cancer; our gene therapy candidates for hemophilia A, hemophilia B and Duchenne muscular dystrophy; our pan-hemophilia A and B antibody treatment; and many more.

If approved, we expect each of these to be key incremental contributors to our growth aspirations through '25 and beyond. Even without any of these additional potential products, we expect our '25 to 2030 revenue CAGR to be approximately 6%. And if some of them are successful, the CAGR could exceed 10%.

Now let me turn my attention to our COVID-19 portfolio. At the JPMorgan conference earlier this month, I spoke about expecting 2023 to be a transition year, representing a low point in our COVID-related revenues. Let me provide a little bit more color on that. I will start with COMIRNATY in the U.S. as an example. In 2022, 31% of the population or 104 million Americans received an average 1.4 doses of COVID-19 vaccines for a total of 144 million doses. COMIRNATY's share was 64% or 92 million of these 144 million doses, as you can see in the first column.

In 2023, we expect about 24% of the population or 79 million people to receive vaccine doses for COVID during this year. This drop is due to expected fewer primary vaccinations and reduced compliance with recommendations. We expect they will receive about 1.3 doses per person on average in 2023. The drop is because fewer people are expected to receive their primary doses and, for the most part, only those who are older or at higher risk are expected to continue receiving more than 1 booster per year. This should result in about 102 million total vaccine doses administered in 2023. We believe Pfizer will maintain at least 64% markets share and therefore expect about 65 million doses of the Pfizer-BioNTech vaccine to be administered in 2023.

In 2024, we expect the utilization rates and market share figures to stabilize and come in roughly the same as in 2023. Then starting in '25 and continuing in '26 and beyond, we expect to see an increase in COVID-19 vaccination rates, assuming the successful development and approval of the COVID/flu combination product. A successful introduction of a COVID/flu combo could, over time, bring the percentage of Americans receiving the COVID-19 vaccine closer to the portion of people getting flu shots, which is currently about 50%. Outside the U.S., we expect these general trends to be similar, with some variations from country to country.

So what does this mean for our revenues? We expect 2023 to be a transition year in the U.S. In 2022, we sold at pandemic prices more doses than were eventually used. This resulted in a government inventory build that we expect to be absorbed sometime in 2023, probably the second half of the year. Around that time, we expect to start selling COMIRNATY through commercial channels at commercial prices. We expect that in years

2024 and beyond, the doses sold and doses used in a year will more closely align together and the commercial price to remain relatively stable with only inflation-like price increases.

Now let me briefly run through PAXLOVID. In 2022, we estimate that 110 million COVID-19 symptomatic infections were reported in the world, excluding China. Approximately 12% of them were treated with approximately 14 million oral therapy courses. And PAXLOVID had the lion's share of them with approximately 90% market share. Average was 86%, but in the second half of the year exceeded the 90%. Keep in mind that this reflects a full year of reported infections, but only a partial year of PAXLOVID availability due to supply constraints in the first quarter of 2022.

In '23 and beyond, we expect infections to increase slightly at 2% annually due to waning immune protection of the population, resulting from reduced vaccination rates. Similarly, we expect treatment rates to increase as awareness, education and additional oral entries will grow the oral antiviral market. Finally, we expect PAXLOVID to maintain very high share despite additional competitive entries, given its strong benefit-risk profile and brand recognition.

So what does this mean for revenues? As with COMIRNATY, we expect 2023 to be a transition year for PAXLOVID as well. In 2022, we sold at pandemic prices more treatment courses than were eventually used. This resulted in a government inventory build that we expect to be absorbed sometime in 2023, probably second half. Around that time, we expect to start selling PAXLOVID through the commercial channels at commercial prices. We expect in years 2024 and beyond, that the courses sold and used will align closely together within every year.

There has been a great deal of speculation regarding the new but uncertain market opportunity for PAXLOVID in China, so let me share what we are seeing. We have an agreement with one company to import and distribute PAXLOVID in China, a local company, and we have a manufacturing agreement with another local Chinese company for local manufacturing. Pfizer shipped only tens of thousands of courses to China in fiscal year 2022. From December, which is the first month of our non-U.S. fiscal year through March, we expect to ship millions of courses to meet local demand.

We expect we will be able to sell effectively under government reimbursement through end of March. And despite China's recent decision not to include PAXLOVID on the country's National Drug Reimbursement List, we expect to offer the product on the private market after April 1 unless, of course, a listing opportunity opens up before then.

Lastly, I want to point out that while we are expecting increased utilization in all regions of the world as infections increase, we are not including any major non-U.S. or non-China contracts in our 2023 forecasts.

Let me close with a few thoughts regarding our scientific engine. R&D continues to be the lifeblood that fuels us as a company, which is why we plan to increase our R&D spend by at least 8.7% in 2023 to \$12.4 billion and \$13.4 billion range. In addition to the increased investments, we are taking steps not only to further improve our industry-leading success rates and cycle times, but also to increase overall return on investment and R&D productivity. As you have seen in the last year, we continuously prioritize our pipeline to focus on the assets that represent potential breakthroughs and have the potential for generating higher returns, putting more capital behind larger opportunities like GLP-1, flu, elranatamab and others.

We are at an infection point -- and we are at an inflection point to act from a position of strength with our best-in-class R&D productivity, a robust pipeline of innovative assets and one of the highest R&D budgets in the industry.

With that, I will turn it over to Dave to provide details on our fourth quarter performance and our outlook for 2023. After Dave, Mikael will provide an update on our R&D pipeline. Take it over, Dave.

David M. Denton - Pfizer Inc. - CFO & Executive VP

Great. Thank you, Albert, and good morning, everyone. Albert has already taken you through many of the key drivers of our full year performance, so I will focus my opening remarks on some key highlights from the fourth quarter. Revenues grew operationally 13%, primarily driven by COMIRNATY's strong growth in developed markets, following the slowdown in deliveries that we discussed in the third quarter, ahead of the rollout of the bivalent booster. We also saw very strong performance from PAXLOVID outside the U.S. and the ongoing launch of Prevnam 20 for adults within the U.S.

Excluding direct sales and alliance revenues related to our COVID-19 products, Pfizer's revenues grew 5% operationally in the quarter. And if recently acquired products from Biohaven and GBT are also excluded, revenues were up approximately 3% in Q4. Reported diluted earnings per share this quarter grew 48% to \$0.87, while Adjusted diluted earnings per share of \$1.14 grew 69% on an operational basis in the quarter. Both EPS figures include a \$0.32 benefit from lower acquired IPR&D expenses compared to last year's fourth quarter.

Once again, in the quarter, foreign exchange movement significantly impacted our results, reducing fourth quarter revenues by approximately \$2.5 billion or 11%, and Adjusted diluted earnings per share by \$0.19 or 24% compared to LY. On a full year basis, foreign exchange negatively impacted revenues by \$5.5 billion or 7%, and Adjusted diluted earnings per share by \$0.36 or 9%.

Turning now to 2023 and the financial outlook for the company. Let me first point out that our approach to guidance in 2023 is fundamentally different than prior years. Given the expected transition to commercial markets for our COVID franchise and away from an advanced purchase agreement environment, our guidance reflects our best estimates for both revenues and profits for these products for the full year, not just what has been contractually secured.

On a total company basis, we expect revenues of between \$67 billion to \$71 billion, reflecting an operational decline of 31% at the midpoint. Importantly, we expect that revenues from our business, excluding COVID, will grow between 7% and 9% on an operational basis in 2023. That growth is projected to be split between contributions from our new product launches, our recently acquired products as well as our in-line portfolio. The total company revenue declines are entirely driven by our COVID products, which are expected to go from their peak in 2020 to their low point in '23 before potentially returning to growth in '24 and beyond. While patient demand for our COVID products is expected to remain strong throughout 2023, much of that demand is expected to be fulfilled by products that were delivered to governments in '22 and recorded as revenues last year.

Now I want to point out that our total company revenue guidance range is wider than what is implied by the 7% to 9% operational growth rate range for the business excluding COVID. The wider guidance range reflects the potential volatility that we see in our COVID product revenues, given that they can be significantly impacted by factors outside our control, such as the infection rates and the severity of the virus as well as the timing for transitioning to a traditional commercial model here in the U.S.

And you can see on this slide our cost and expense guidance for '23. As I mentioned in my remarks at our investor event in December, both SI&A and R&D expenses are expected to be significantly higher in 2023 versus '22, despite the fact that our overall revenues are coming down. Higher investments in SI&A are significantly focused on the successful launches of the large number of potential new products that Albert highlighted as well as recently acquired assets. Additionally, the expected commercial launch of both COMIRNATY and PAXLOVID in the U.S. will require additional investments as we transition away from the government market. These investments are squarely focused on supporting the company's 2025 to 2030 growth aspirations.

We also intend to invest significantly in our research efforts this year, with multiple exciting and potentially high-value programs receiving additional funding, including our oral GLP-1 programs, elranatamab and respiratory combination vaccines. All of this spending to support our commercial and research activities, we believe, will not only yield an attractive return but also contribute toward setting us on a path to achieving our long-term growth goals.

I'd point out that when you exclude revenues and expenses related to our COVID products, our expected operating margin profile this year is largely consistent with the prior year. This reflects incremental investments in SI&A related to launch products and R&D as well as lower acquired IPR&D expenses.

In 2023, we are investing in both R&D and SI&A in advance of revenue contributions from new products. Looking longer term, we expect this spending will be maintained with the P&L growing into this cost base as new product revenues begin to be fully realized, with margins improving as a result. Given that 2023 is both a year of investment and transition, I thought it would be helpful to outline many of our key assumptions built into our guidance. I don't intend to walk you through all of the elements here, but both Slides 19 and 20 outline many of the details.

In summary, these assumptions include strong revenue growth of 7% to 9% in our business, excluding COVID; additional investments in SI&A and R&D to support Pfizer's near- and longer-term growth plans; continued patient demand for our COVID-related products worldwide, with vaccination rates declining slightly and utilization of treatments slightly increasing; rephasing of the European Commission COMIRNATY contract over multiple years versus full delivery in 2023; and finally, U.S. commercialization of the COVID products in the second half of 2023.

In summary, as we enter a new year, our business is extremely strong with many in-line, acquired and expected launch products capable of driving strong growth with an attractive pipeline of potential products coming in the future. We believe '23 will be an important year for Pfizer, and that is why we are deploying our resources into quality execution in order to fully realize the growth opportunities we see within our portfolio and within our pipeline, which have the potential to impact our growth outlook through 2030 and beyond.

So with that, let me turn it over to Mikael.

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

Thank you, Dave. Today, I want to set the stage for an anticipated catalyst-rich 18 months. As Albert mentioned, we are in a position of unprecedented strength in our history, and I'm excited to share a high-level overview of an evolved strategy for Pfizer R&D to focus our resources on transformative programs which could be most impactful for patients, drive improved return on R&D investment and create the most value. We will leverage and continue to innovate our powerhouse capabilities in medicine design and continue to innovate light-speed drug development to further improve our industry-leading success rates and cycle times.

We have rethought our approach to rare disease and will move from having a stand-alone research unit to aligning key programs with other therapeutic areas. We plan to externally advance rare disease programs that do not fit into a core therapeutic area of focus. At the same time, we plan to tap into the expanding external innovation ecosystem by actively pursuing biotech innovation and emerging innovation that fits strategically and accessing external assets that are differentiated. Taken together, we believe these actions will help position us to lead the industry in reaching more patients with the most impactful near-term blockbuster breakthroughs while driving forward the next wave of innovations.

I'm pleased to share some examples with you today. We are pursuing potentially transformative efficacy in our Inflammation & Immunology franchise, with the potential launches of etrasimod in ulcerative colitis and ritlecitinib in alopecia areata, which both have the potential to be blockbusters, and a planned Phase III study start of anti-interferon beta in dermatomyositis and other idiopathic inflammatory myopathies. Our next wave of innovation includes 2 monoclonal antibody candidates for atopic dermatitis, which exemplify our multispecific platform and in-house biomedicine design expertise.

Two assets currently in Phase 1 clinical trials each targets 3 cytokines in a single therapeutics, so we refer to them as trispecifics. On the right are Phase 1 pharmacokinetic profile of the average plasma concentration. For both molecules, the profiles suggest that once a month or even less frequent, subcutaneous dosing may be supported. There is potential for improved efficacy with more potent interleukin-4 and 13 utilization plus an expanded breadth of efficacy by blocking thymic stromal lymphopoietin to potentially cover more endotypes or by blocking interleukin-23 to potentially enhance itch reduction.

The Phase 1 studies continue. We aim to bolster our 30-year experience in hematology with a strong pipeline that complements our in-line portfolio and collectively has blockbuster potential. I will talk more about elranatamab and GBT601 in a moment. So will highlight here that we expect multiple data readouts for TTI-622 in hematological malignancies, 2 Phase III readouts for inclacumab in sickle cell disease in the second half of '24 and a Phase 3 readout for marstacimab in patients with hemophilia A or B in second quarter of '23.

Marstacimab has FDA Fast Track designation for both hemophilia A and B with inhibitors. If successful, we project submitting for the non-inhibitor indication in both A and B hemophilia in the third quarter of '23. We recently announced positive top line results from a Phase 3 study of our hemophilia B gene therapy candidate and expect the pivotal readout for our hemophilia A gene therapy in the first half of '24.

We recently presented strong updated Phase 2 data on elranatamab, our investigational B-cell maturation antigen, or BCMA, CD3-targeted bispecific antibody for relapsed or refractory multiple myeloma in heavily pretreated patients who had received at least 3 classes of prior therapies. This

candidate, which has the potential to be a leader in the BCMA bispecific class, demonstrated a high objective response rate of 61% in patients with no prior BCMA-targeted treatment, early and deep responses and a manageable safety profile.

Given factors currently limiting the availability of novel therapies in the triple-class exposed setting, elranatamab has the potential to reach a broad and greater number of patients as an off-the-shelf option with reduced dosing frequency that is administered subcutaneously, offering more convenience than intravenous administration.

With FDA Breakthrough Therapy designation granted last year, elranatamab could potentially be approved this year. As there is blockbuster potential and patient value beyond the triple-class refractory population, our clinical strategy aims to move to earlier lines of therapy and combination approaches with the potential, if successful, for multiple approvals to expand eligibility and duration of therapy.

Now to our next-generation oral, once-daily hemoglobin S polymerization inhibitor candidate that's in a unique class and has the potential to expand the prophylactic treatment of people with sickle cell disease. Standard-of-care treatment rates have typically been low due to side effects, poor efficacy or both. While Oxbryta made substantial progress in preventing hemoglobin polymerization or sickling, GBT601 is a potentially best-in-class candidate, which may reduce both hemolysis and frequency of vaso-occlusive crisis.

The most recent data from our Phase 1 multiple-ascending dose study showed improvements in hematocrit and hemoglobin levels over time, mean hemoglobin occupancy of more than 32% for the 100-milligram maintenance dose and more than 41% for the 150-milligram maintenance dose and improvements in red blood cell health with the higher maintenance doses. The maintenance doses were well tolerated.

We believe these results may be transformative for patients, with a potential to achieve 35% to 45% hemoglobin occupancy, which is considered optimal for both hemoglobin oxygen affinity and preventing sickling, and approaches levels seen with gene therapy. This asset is also being studied in an ongoing Phase 2 study with a seamless Phase 2/3 design. We plan to start the Phase 3 part in the second half of 2023.

Next, we aim to expand our leadership in breast cancer with a pipeline of complementary next-wave candidate. Our CDK4 inhibitor targets improving on CDK4/6 inhibition standard of care by maximizing CDK4 coverage. We're studying it in Phase 1 in hormone receptor-positive, HER2-negative metastatic breast cancer as a single agent and in combination with endocrine therapy. The majority of hormone receptor-positive breast cancers express low CDK6, while CDK4 is likely to be a major cell cycle driver. We have seen that CDK4/6 inhibition can lead to neutropenia that requires more frequent blood test monitoring, mostly driven by CDK6 inhibition, and that complete CDK4 inhibition by these inhibitors is challenging due to dose-limiting hematological adverse events.

In the Phase 1 combination study, the confirmed objective response rate in combination with fulvestrant or letrozole reached nearly 30%. And the clinical benefit rate was approximately 50% in 21 patients with measurable disease. The median progression-free survival was more than 24 weeks in 26 patients, including 5 without measurable disease. All patients were heavily pretreated with a median of 4 lines of prior treatment. All patients received prior CDK4/6 inhibitor treatment and 67% received prior fulvestrant. The asset was well tolerated with the CDK4 drug showing only 15% Grade 3 neutropenia and no Grade 4.

Here we show a scan of a patient who achieved partial response and was on treatment for 47 weeks. She had received 6 lines of prior treatment, including CDK4/6 inhibition and fulvestrant. We are currently engaged in dose optimization, enrolling CDK4/6-naïve cohort and planning to start a randomized study in second-line treatment of estrogen receptor-positive, HER2-negative metastatic breast cancer this year. Additional data readouts from our next wave of breast cancer candidates are anticipated in the first half of '23.

In addition to the assets I spoke about today, we anticipate multiple milestones over the next 18 months. We expect a pivotal IBRANCE readout in hormone receptor-positive, HER2-positive metastatic breast cancer, a pivotal study start for ARV-471 and a Phase 2 readout for our KAT6 inhibitor. We have achieved incredible advancement in our vaccines portfolio, including candidates that harness our leadership in mRNA with an unprecedented number of milestones expected. In addition to the expected launches shown here, we expect a Phase 3 data readout from our modRNA flu candidate vaccine and a potential respiratory combination vaccine study start.

A Phase 1/2 study of our shingles candidate, the first mRNA-based shingles vaccine program began last week. In Inflammation & Immunology as well as Internal Medicine, key catalysts include potential launches of potential blockbusters, a planned pivotal study start with [interferon beta map] and data readout in metabolic disease.

We are also making good progress in our anti-infectives portfolio, including anticipating full approval for PAXLOVID and planned study starts for both our second-generation COVID-19 antiviral candidate, which may have no or limited drug-drug interaction and our RSV antiviral candidate.

In closing, we are very optimistic about the many transformative catalysts emerging from the pipeline. Pfizer's scientists are working with urgency and commitment to help the most patients as quickly as we can.

Thank you. Let me turn it over to Chris to start the Q&A session.

Christopher J. Stevo - Pfizer Inc. - Senior VP & Chief IR Officer

Thank you, Mikael. Chelsea, why don't you poll for questions, please? We'll take as many questions as time permits, and Investor Relations will be available after the call to answer any detailed questions that we're not able to address on the call itself.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And we'll take our first question from Louise Chen with Cantor.

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

So first question I have for you is do you expect your COVID/flu combo to be on an mRNA platform? And then I wanted to ask you on this RSV vaccine, there's a few players in the space. And I'm just wondering if you think anybody could potentially get a preferential recommendation from ACIP. Or is that really hard to achieve? And the last question is on your trispecific monoclonal antibody. Is atopic dermatitis still a key focus for you? And if so, are you moving the focus to this monoclonal antibody? Or are you still focused on etrasimod for atopic dermatitis? And also, you had an oral PD -- sorry, a topical PDE4 that was in development.

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

Thank you, Louise. Clearly, for the ACIP, will depend on the data. And it's difficult now to say if a preferential could be achieved or not. But for both questions, COVID/flu is mRNA; RSV is not, Mikael, and then also what about the trispecific antibodies?

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

So as Albert spoke about CIBINQO's expansion, we think there's room for many opportunities in atopic dermatitis. We wanted to highlight this as a really novel, pioneering approach to go beyond the current antibodies in atopic dermatitis with potentially many other allergic diseases. But there is room for several products in our pipeline in both oral and topical segment, as we mentioned. So this is an area, I think, we will excel in.

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

And what about COVID/flu that is mRNA and RSV that it is not an mRNA. How do you think about it?

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

Well, I think it actually offers an opportunity when you have the breadth to have a pipeline with different platforms. We think that the COVID/flu, which contains 6 components, and we have made a real good progress in enrolling the study and we'll start to share data in the near future has, by itself, of course, a Fast Track forward pending data. But for the use of a potential triple vaccine, rather than adding up more and more mRNA, with the current technology that we have seen, can lead to reactogenicity limitation and less tolerability. We think this flexibility to add on a protein may give you the perfect balance between efficacy and tolerability.

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

Thank you, Mikael. And also to -- as you know, we are mastering multiple technology vaccines, so we are using fit for purpose here. Every time we feel that a technology is appropriate for the problem we're trying to solve, we apply this technology. Flu and COVID, they are -- speed is of essence because there are variants that are coming. So mRNA is ideal position to address this challenge.

With RSV, the virus is not changing that often. So a protein approach that has a brilliant tolerability profile, almost like placebo was when we saw the data, the responses of the vaccine arm compared to the placebo arm were very difficult to separate. With very, very high efficacy in our case, I think it's the best way to move forward. That's the benefit of having multiple approaches and multiple technologies.

Operator

Our next question will come from Terence Flynn with Morgan Stanley.

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

Maybe two parts from me. Was just wondering if you can provide any more details on the European vaccine contracts that were extended. Just wondering if you were able to secure a higher average price, given some of the headlines in the press earlier this week. And then latest thinking on PAXLOVID commercial pricing in the U.S. as well. Was wondering if you could weigh in on that. And then the second question relates to economics with BioNTech on a combo vaccine. Just wondering how that will work in the event that you do go forward with a combined COVID and seasonal flu messenger RNA vaccine.

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

I'll take the last one and then Angela will answer the European vaccine and the PAXLOVID. As you know, the flu vaccine that we are developing, BioNTech also have an economic position into it. And of course, the COVID vaccine, it is a vaccine that we are sharing with them. So we are not ready to make any comments regarding the economics about the potential COVID and flu vaccine. Angela, what about the European situation and PAXLOVID pricing?

Angela Hwang - Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business

So for COMIRNATY in Europe, as you know, this was a multiyear contract that we entered into with the Commission and the member states. And so I think the pricing there is what it is for the contract, and we're in discussions with the European Commission regarding '23 and what the deliveries will look like. Specifically for PAX, I think that was your next question, that is going commercial only later in this year so we are now preparing what those pricing scenarios could look like, and we'll share more at the right time.

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

Thank you, Angela. And also to repeat, I think David has mentioned it already that in our guidance for this year, we factor only a portion of the European contract. So we spread the volumes into multiple years, although no agreement has been reached yet.

Operator

Our next question will come from Robyn Karnauskas with Truist.

Robyn Kay Shelton Karnauskas - Truist Securities, Inc., Research Division - Research Analyst

So just to drill down a little bit on PAXLOVID. It looks like IQVIA numbers are implying about 9.3 million versus, say, the 12 million that you mentioned for 2022. So I was wondering if you think about the split going forward ex U.S., could it be somewhat similar? Do you think it'll be more skewed to be more even between the U.S. and ex U.S.? And then my second question is, it also could imply that about half of your 20 million contracts were used in 2022. So how do you think about -- could it be very minimal revenue as you draw down that PAXLOVID and will that go into a stockpile?

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

Angela?

Angela Hwang - Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business

Sure. Well, let's start with the U.S. PAXLOVID. So in 2022, when we launched PAXLOVID, we -- the first quarter of PAXLOVID, the first quarter post launch, we did not really have sufficient supply because we were still ramping up. So the total number of doses that were used in the U.S. for PAXLOVID is actually less than the demand. So that's why you see that we used about 8.6 million, 8.9 million doses in the U.S. when actually demand was much more than that.

Then you asked a question about IQVIA, the difference. As you know, IQVIA doesn't capture all the channels, so you're not going to see an exact match. But I think that in general for 2023, the number of doses that you will see for the U.S. and for ex U.S. is just going to be a function of the contracts that were made, the deliveries that we have to make in each of the countries and also the timing of the commercialization. And it just looks different in every single country.

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

Thank you, Angela. And also to emphasize that the 12 million calculations are a global number, not a U.S. number. It's a global number. So I believe the 9 million of IQVIA is approximately in the U.S. And -- but I don't know if they have also estimations for outside the U.S. The global number exclude -- I'm sorry for the clarification. It's a global number, excluding the 12 million that I mentioned.

Operator

Our next question will come from Geoff Meacham with Bank of America.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Just have two. The first one is on COVID. When you look at the 2023 demand and beyond really for both products, I guess I'm trying to better understand the volume side of the equation. Are you guys baking in the emergence of, say, a new variant or maybe a change in behavior towards boosters? That's the first question.

The second one is, from a BD perspective, Albert, you have a lot of cash to deploy. If your COVID assumptions don't quite play out, does that inform the number of deals or the size of deals? I guess I'm trying to get a view about where BD fits in your strategic priorities.

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

Of course. First, what is the assumption about the disease because that's a fundamental assumption behind all these projections that we are doing. It is that the disease will continue in the foreseeable future, manifesting clinically the same way that it does in the last 6, 9 months. So there will be mutations and there will be infections over there. And -- but the vaccination rates will be coming down because of lack of compliance but will stabilize to a certain degree of people because they believe in vaccinations and they feel they are at high risk and they want to make the vaccines.

At the same time, the infections were slightly going up because when you have waning immune protection for the population, then you will see more infections and actually more severe infections. So these are the assumptions that we are using. We are not using assumptions that all the variants we will have will escape the protection of the vaccine. But we are using the assumptions that people will be getting 1.3 in the beginning and then going down 1.1, 1.2 doses per year as a normal booster.

What was the second question? On the BD, yes. Clearly, business development is, by far, one of our biggest priorities, something that I personally take care of and something that we have a very big team screening all the opportunities. I would like to ask Aamir, who is responsible for that area, to make some comments about our priorities.

Aamir Malik - Pfizer Inc. - Executive VP & Chief Business Innovation Officer

So Geoff, specifically to your question, you heard Albert described, we set this aspiration goal of \$25 billion in 2030 from BD, we're over 40% of the way there with approximately \$10.5 billion of that number through the deals that we've done. And we feel very confident that we've got the financial flexibility on the balance sheet and the firepower to complete what we need to, to achieve that goal. And we're going to continue to be disciplined about how we pursue that.

Operator

Our next question will come from Steve Scala with Cowen.

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

I have a couple of questions. On Page 4 of the release, Pfizer reiterated that non-COVID revenue growth in 2023 will be 7% to 9% and anticipates it will be split between launch, acquired and in-line products. That implies about \$3.5 billion in incremental revenue growth. But in 2022, Prevnar alone grew \$1 billion, and Eliquis and VYNDAREL together added another \$1 billion.

So with the launch and acquired products growing well, what does this guidance imply for the base business in 2023? It seems like a substantial slowdown is implied in the base business in the current year. Second question, has Pfizer learned anything from the ZEPOSIA performance to date that would either increase or decrease its confidence in etrasimod?

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

I would say, Dave, do you want to say how it's allocated, the growth between in-line, new products and acquired products?

David M. Denton - Pfizer Inc. - CFO & Executive VP

Yes, a really good question. I think if you look at each one, each of those 3 buckets, we see growth from acquired products, we see acquired from new products. And importantly, we see growth in our in-line portfolio as well. We do not anticipate nor do we see a slowdown from that perspective.

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

It's approximately 1/3, 1/3, 1/3. And Angela, what about the etrasimod?

Angela Hwang - Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business

I think we're really excited about etrasimod as a new entry in UC. It's a market that has been heavily dominated by biologics and then followed by the use of JAKs after the biologics. But really, in the earlier treatment positions, there really hasn't been much innovation, and that's where we see etrasimod fitting in. I think the safety profile of etrasimod and its efficacy allows it to be used very well as an agent prior to the use of biologics. And that's where we see the ability to tap into a new segment and to grow.

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

And because I'm very excited about the product, William, would you like also to add something about it?

William Pao - Pfizer Inc. - Executive VP & Chief Development Officer

Yes. I would just say we're excited about the best-in-class profile with the study that we did had a treat-through design. We hope and anticipate that we'll have no black box warning. We don't anticipate any requirement for titration. The once-oral dosing, 100% of our patients were in complete remission after a year and we're still -- that were in complete remission after 1 year were steroid-free. And we also have quick lymphocyte recovery after discontinuation. So we feel all of these features potentially make etrasimod a best-in-class profile.

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

Sure. That's exactly the point. Best-in-class in an area that it is poorly served right now with current solutions, so we see a lot of opportunity.

Operator

Our next question will come from Colin Bristow with UBS.

Colin Nigel Bristow - UBS Investment Bank, Research Division - Analyst

I guess first question on COVID and to sort of piggyback on what Geoff was asking. I mean from your slides and comments, you're clearly expecting a sort of stable vaccine utilization rate when, in the last 12 months, we've seen this number decline on a backdrop of a virus that is evolving to less clinically severe variants. And so what underpins your confidence in these longer-term assumptions?

And then also in terms of your COVID '23 guidance, you mentioned you'd guided to a sufficient range of variations in infection rates, et cetera. I was just wondering how much an allowance you've made for the potential timing or reduction in contractual orders as is the current situation with the Brussels negotiation? And then maybe just a quick one on the pipeline DMD. This feels noticeably in the background versus other assets at a similar stage. Just could you update us on your level of enthusiasm and commitment to this program, especially in light of the potential competitor approval in May of this year?

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

Thank you. DMD, Mikael?

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

We continue to be enthusiastic about gene therapy in DMD. I think we have actually published the strongest data on the 2 drugs with efficacy as well as a lot of biomarkers from our Phase 1 across a much broader age group than anyone else. And I can't comment when possibly someone else will get it registered, but we expect data readouts within possibly less than a year. And we think that this could be a very important drug. And we will have randomized data, which is not the case for any other application currently to have at that size and scope.

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

As regards the assumptions of our COVID protection vaccines, for example, we are dropping the numbers. So for example, 31% of people receiving a vaccine, that was the actual in '22, we are going to 24%. Then you are reaching a level of really people that they are really committed to the idea of getting vaccinations and they are looked by physicians that they truly believe in the vaccination, the value of vaccinations.

We are also dropping the number of doses there. So we'll go to 1.3. And then eventually, as the years progress, the number of doses that people will receive is small. Keep in mind that to get numbers like 1.2, you need a very, very small percent of the population to 2 doses so that you can achieve something like that. Maybe 5% of the population will get a second dose, and then you will go to these numbers, as you will see if you include also primary doses and children.

So we believe the assumptions are very reasonable with the expectation that COVID will remain as it is right now. So nothing more severe and nothing that will make it less severe, and we take into consideration that the compliance with the recommendation of the health authorities also because of the fact it will be less. Clearly, pivotal moment will be the introduction of combination vaccines because the convenience or something like that and the fact that people are presenting themselves to receive flu vaccines, given that a combo vaccine would be in the same injection and will cost 0 co-pay likely will become the choice of many to get this full coverage.

So we are quite confident on these assumptions. But of course, they are only assumptions. We need to wait and see. The other thing it is on the Europe, you asked a few questions. I know that there are rumors, but I don't think that it is appropriate for us to make any comments while we are in negotiation with our partners in the Commission and with the member states. So we only said that we factor on part of the deliveries in this year instead of all the deliveries because we are in the middle of negotiations, but we can't make other comments.

Operator

Our next question will come from Trung Huynh with Credit Suisse.

Trung Chuong Huynh - Crédit Suisse AG, Research Division - Research Analyst

It's Trung Huynh from Credit Suisse. I have a quick clarification on COVID and then my question. So just on the clarification in those long-term COVID vaccine and PAX slides. Do you expect any U.S. government sales in '24 and '26? It just looks like commercial sales on your slides. So does that mean Medicaid, Medicare populations are bought at a commercial price? And can you comment on the margin change for the vaccine and PAX as you step up to that commercial price?

And secondly, just following on from the base business question from Steve. We saw lower revenues ex U.S. for some important base business drugs. So Eliquis was down 19% ex U.S., IBRANCE down minus 22% ex U.S. Plevnar, there was also a decline there. You've noted some product-related

issues, but are you seeing anything more broadly in the U.S. which is making it a more difficult environment? And going forward, should we expect more normal levels ex U.S. for these products?

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

A quick one because that's easy. We do not expect '24 and '25 and beyond to have governmental sales in the U.S. In fact, we think that not even this year, other than some small deliveries that we have still pending with the U.S. government from the coronavirus before. We will not see any U.S. purchases. That's our assumption right now, that we will move into a commercial model that will cover all channels as with all other vaccines and products.

Margin changes, we haven't said anything yet about PAXLOVID so I can't comment, if you can calculate. We set the risk price, you can calculate the net and then you can make your assumptions on margins. We don't give margins on specific programs. Now a little bit on the lower revenues -- about the revenues ex U.S. Angela, do you want to make any comment on that?

Angela Hwang - Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business

Sure. As you said, there were some specific reasons for why we saw what we saw for Eliquis, IBRANCE, PCV. I mean Eliquis specifically was the loss of exclusivity and our patent challenges that led to some generic increase at risk in both the U.K. and Netherlands. I mean IBRANCE is a mature product, and so it goes through sort of the reimbursement and the sort of the pricing regulation that it typically goes through in Europe. And I think PCV in general, what we're seeing is that, at least on the peds side, not on the adult side but on the peds side, vaccinations are still are not back up to where they are, where it was prior to the pandemic. So I think in all 3 cases, there were very specific reasons for what you saw. And we don't anticipate anything extraordinary or different in 2023. I think it's sort of business as usual.

Operator

Next question will come from Tim Anderson with Wolfe Research.

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

I think one of the challenges for analysts modeling Pfizer is to try to understand what the flow-through to profitability is from PAXLOVID and COMIRNATY. So I'm hoping directionally, you can tell us how that looks going forward once you get past this transitional year of '23. So in '24 and beyond, is the profitability of that combined franchise likely to be higher, less or the same as what it was in 2021 and 2022? And then a second question is on SG&A. How much of that increase was driven by inflation in 2023? And just any quick comments on European austerity measures on the pricing.

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

Dave?

David M. Denton - Pfizer Inc. - CFO & Executive VP

Yes. So on -- maybe on the COVID franchise, obviously, we don't give profitability for each product. But you can imagine, as we stated before, on the vaccine, we split our gross margin with BioNTech. So therefore, that would obviously carry a lower profitability mix compared to a typical product. And PAXLOVID is probably the opposite in the sense that we share that, the economics of that fully. So it's probably a bit on the larger higher-margin side in general. That's...

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

And one, you can predict that, for example, in the first years '21, '22 had very high R&D expenses also. We maintain our R&D expenses of COVID. A very big part of our expenses in '23 is for COVID because we are investing. But we expect over time those, unless if we bring new products that will not be as high as. On the contrary, price are going up, that says that margins could improve. But also S&A, promotion expenses are going up, right? So without wanting to give direction from what it used to be '21, '22, likely, we expect going forward to be higher, the margins. But all of these equations will be in play.

Operator

Our next question will come from Mohit Bansal with Wells Fargo.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Maybe one question, if I can ask. So regarding the expenses for COVID business, Dave, you mentioned that you will be essentially relaunching these products with the commercial scale and everything. So is there -- so how much cost, given that your COVID business is declining significantly this year, are you modeling any kind of cost cuts in that business? Or should be more on dollar basis are still the same? And is there any synergies you can achieve especially for vaccine with your existing Prevnar business because the channels are similar or not? And last part is, do you think you can do more share buybacks given the stock price at this point?

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

Let me take the first two quickly. Of course, as you saw, the business is going down. Because of COVID, the average is growing. Expenses are going up because we are promoting new launches, including COVID. So right now, moving into COMIRNATY in commercial and PAXLOVID with the commercial channels, now we treat them like normal promotional products, very sensitive in promotions at the beginning of their launch. So we are going very hard with promotions, TV, field forces and all the other educational measures that we are taking when we do this type of launch. So there is -- clearly this space. What about, David, are we going to buy back?

David M. Denton - Pfizer Inc. - CFO & Executive VP

Yes. So a really good question. I think as we look at capital allocation at this point in time, we actually see a lot of opportunities to invest back into our business, both from a research perspective and importantly, getting behind our launches to make sure that we're doing all that we can to ensure that our growth trajectory in '25 and '30 and those goals and aspirations become reality. So I think our best and highest use of capital right now is investing in our business, both internally as well as from a BD perspective. I would say never say never to an incremental share repurchase, but that's not high on the priority list at this point.

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

And Mohit also, you asked also about the synergies, it's clear. There are a lot of synergies right now, both in the PAXLOVID. PAXLOVID is covered by a lot of physicians, and we have very, very strong primary care field force and we have a very strong also vaccines field force that is covering all these physicians that are either vaccinate or prescribing PAXLOVID. So clearly, a lot of synergies in retail and in the medical profession relationship.

Operator

Our next question will come from Chris Schott with JPMorgan.

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

Just building on some of the OpEx discussion here. I just want to make sure I'm understanding the OpEx dynamics properly over time. So I guess should we think about 2023 as more of a onetime step-up in OpEx and then much slower growth in '24 and beyond? Or should we be thinking about this as a couple of year process as you really get the pipeline and new products ramped, and then it's maybe more second half of the decade before we think even about margin -- bigger margin expansion or that OpEx slowing? I just want to make sure I'm seeing those dynamics properly.

And then the second one was on the COVID/flu combination. I guess is your expectation that the tolerability of that will be similar to what we see with COMIRNATY? Or is there some trade-off of we could see maybe slightly higher kind of side effects for the 6 components you mentioned but that's offset by the convenience? I'm just trying to make sure I understand what your expectations are for that program.

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

Thank you very much, Chris. To this scientific question, to Mikael first.

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

Yes. We think that the tolerability will be well on par with vaccines used in the target population and be perceived as tolerable and convenient. As you described, the combination will attract the high volume of flu people to also be able in one shot to renew their COVID coverage, particularly with more and more variant coming. So we are very positive and think we are right in the balance of those and opportunity there.

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

Thank you. And of course, the data will say, but right now, this is the profile that we are targeting. And we think it's easy to do it with 2 viruses, so to load enough so that you have very good efficacy and good tolerability profile. We believe it will be more challenging for 3, but of course, needs to be seen. And that's why we believe that our RSV protein and having such a good tolerability profile offers better combination of a triplet, then triple it all with mRNA. Dave, also there was this question that I think you touched upon it earlier in your script about how we see going forward the expenses of SI&A.

David M. Denton - Pfizer Inc. - CFO & Executive VP

Yes. So importantly, 2023, we're seeing a step-up in SI&A and it's really, again, investments around the launches and the products that have been acquired, which we think are really important to really drive growth in the back half of the decade. So we're already focused on that. We do think '23 is probably the big year of step-up from expenses. And then post '23, these expenses will grow more moderately after that.

Operator

Our next question will come from David Risinger with SVB Securities.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Thanks for all of the additional details that you're providing. So it seems like the 2023 guidance is conservative, which is encouraging. But looking to PAXLOVID longer term on Slide 11, I guess I'm surprised that the percentage of symptomatic patients that you expect to be treated with an oral therapy would almost double from 12% to 22% between '22 and '26, even though the pandemic is being viewed as being over. So I'm hoping that you could talk a little bit about those assumptions and what the denominator is. So when you say symptomatic patients, is that high-risk/elderly that you're calculating the 12% on going to 22%, et cetera?

And then in terms of the PAXLOVID share, it was approaching 91% at the year-end of '22, according to this slide, but only declining to 80% in '26 when there are several companies, both large and small, ranging from Gilead to smaller companies that are planning to develop agents to compete aggressively, and that could have implications for both volume and pricing longer term. So wanted to understand that.

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

David, very good question. So let me try to explain a little bit. First of all, it's not 12% going to 22%. It's really 17% going to 22%, right? The 12% which is in '22, it is a partial year, so it didn't include the full year. The real demand, it is, let's say, '23 full year, it is 17%. And it's going up because of two factors: one, it is a small increase in infections. And as I explained, the assumption is that COVID will not disappear, will be there. But vaccine rates, vaccinations are going down. So that will create -- will wane the protection, the new protection of the population. And that will manifest with a small increase, which you factor at 2% based on our modeling, a small increase of both the infections and I mentioned also the severity. So that's one.

So the second is that the more introductions of new entries likely will not happen before '25, '24, '25, in the U.S. at least. Will depend if EUA will still be available, which will depend if we will be in a state of emergency or not for EUA. But if we will not be in a state of emergency, which could be likely the scenario, there will be no EUAs, and we don't see in '24 any introduction, actually we see in '25 the introductions. The introductions though, also, as always, are increasing the overall cost share, so that is what also is driving. We are dropping market share but we are increasing the volume.

The last is are we dropping the market share aggressively enough or are we, let's say, very optimistic in dropping. The assumption here it is that we are the only one which have right now, for years, presence in the market with a label that is extremely strong with 86% clinical efficacy against hospitalization and against death, high actual against death. So it's very difficult for anyone to reproduce this data right now. The studies will run forever likely and will be very large. So very, very difficult to reproduce something like that.

So as a result, given that for years, we will be among -- we will be basically the lion market share, plus the excellent profile, the loyalty that will be developed. All of that are telling us that it is very reasonable with -- to maintain very high market share into, and we see that, in first in class. And it's in every treatment, from cancer to that compared to the second and third, it's easy to maintain 60%, 70% of their overall conditions. Now that we have all these advantages, we think maintaining at 70%, 75% I think is reasonable. Of course, we'll have to see.

Operator

Our next question will come from Chris Shibutani with Goldman Sachs.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Two questions. One on PAXLOVID cross-currents there between China in terms of the millions of doses that you described for your first fiscal quarter and a potential transition into a private market in China. And then the U.S. where a similar transition will occur to the commercial. Can you help at all frame what you think the relative contributions could look like in '23 and how that could progress?

And then in particular with regard to the transition to commercial markets for the COVID franchise products, can you share any early color on the discussions or engagement that you're having with payers? What kind of dynamics? Any color there would be helpful, particularly in the broader context of a global pharmaceutical opportunity with many different therapeutics that will be on their list of budget items, obesity, Alzheimer's, et cetera. So any color on the discussions with payers would be helpful.

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

Yes. Thank you. Angela?

Angela Hwang - Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business

Sure. So I think for PAXLOVID, again, the time period, the way to think about it is in 2 time periods from now until April, which is a reimbursed market, which gives us access to both public as well as private channels. And then after April, private channels only. As you heard, we have included in our guidance what we believe we can do in the first 3 months of this year. But given the fact that the back half of the year, we will -- it's going to be highly uncertain. It will be a very dynamic market. We'll continue to make sure that we have supply, but we'll have to just wait and see what happens there.

On the side of...

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

U.S.

Angela Hwang - Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business

U.S., similarly, we will be transitioning this year. We will have a year where some of the revenue will be made through the completion of contracts that we made with the U.S. government in 2022. And then part of the year, the revenues will come from the commercialization of PAXLOVID. So you're going to see that play through -- both of those dynamics play through. And then I think you had one more question.

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

Yes, the payers. What is the reaction with the vaccine or...

Angela Hwang - Pfizer Inc. - Chief Commercial Officer & President of Global Biopharmaceuticals Business

Yes. Yes. So it's still early days, especially in the U.S., right, because that's only happening middle of the year. But what I can say is that we have had some early discussions already with agencies and reimbursement agencies outside of the U.S. who have given us, I guess, earlier feedback. And even if you take a country like the U.K., we actually had very favorable feedback on the pricing that we provided, and they agreed with the cost effectiveness of our PAXLOVID. So I think we'll -- obviously, that's good feedback, and we'll be taking those learnings and those value arguments to multiple countries around the world.

Operator

Our next question will come from Carter Gould with Barclays.

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

And David, thank you for all the transparency on the underlying assumptions. I guess two from me. First off, just in terms of the upcoming, I guess, messaging around the end of the public health emergency. Can you talk about the potential impact you see on your EUAs, access as well, specifically thinking about PAXLOVID populations in this period before we switch to a commercial market where you're still -- the government is still, I guess, working through the inventory they have in hand?

And then going to the COVID/flu combination, just trying to better understand some of your assumptions here. Because I guess when we think about that '26 40% adoption number, it's some -- I guess, either the incremental bump from 24%, 15% or the 40% absolute, just kind of what that

implies about how you think the underlying flu market will change. So I guess that comply 30% to 80% share within 2 years, but just wanted to understand kind of the underlying drivers there and how you think about that market evolving.

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

Thank you. Maybe I'll try myself quickly because we're running out of time. If there is an end of emergency, we don't think that will have any impact on current EUAs, won't have an impact on issuing new EUAs. I don't think that anything changes in the way that -- emergency or not, whether the inventories will be managed or the access that patients will have in any of these treatments.

Now as regards to COVID/flu, if the introduction of combination for products would change the flu market, I think, yes. Well, would say it's a major flu market was always a single market until now. And suddenly, there is a chance that other respiratory diseases like COVID or RSV will come. So I think that would change. And now the step-up, it is clear we expect that around 24%, 25%, it is a population in the U.S., that believes needs protection and is diligent enough -- not believes, more belief, but they are diligent enough to follow the recommendation and go and get their annual booster for COVID.

When they will present themselves -- excuse me, when the flu people will present themselves and they will be asked the question, if you want flu single or flu with a combo, and they will be given the information that will protect them in a single injection at the same time, 0 co-pay for COVID as well, we believe it's reasonable to expect that the 25% stable will become 30%, so will add another 5% of the population. And that over time, that will move closer to the 50%. We projected 40% over there. So those are the assumptions that we're using.

Operator

Our next question will come from Kerry Holford with Berenberg.

Kerry Ann Holford - Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst

A couple of questions on vaccines, please. Firstly, on RSV, can you confirm you're on track to provide that second season of data ahead of approval and reimbursement discussions in May-June for the older adult vaccine? And can you confirm whether you've now filed your maternal RSV vaccine with the regulator? If not, are you waiting for the approval in the older adult setting first? And then just on the flu/COVID combo, if we assume you have positive flu Phase 3 data in the second half of the year, positive Phase 1 combo data in the first half, would you expect to move the combo into Phase 3? Or is there a possibility you will not need a full Phase 3 combo study to proceed to filing an approval?

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

Mikael?

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

Yes. I mean we always follow multiseasonal vaccines, and we'll share the second season data as soon as it's available. Of course, there are many ways this can play out with combination vaccines and which could lead to more regular vaccination rather than protracted. And on -- you also asked about the, let's see, the flu/COVID combo here.

Christopher J. Stevo - Pfizer Inc. - Senior VP & Chief IR Officer

Will we need a full Phase 3 trial or...

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

Yes.

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

So if we need a full Phase 3, if we have both flu and COVID.

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

We expect that you need a Phase 3 that is based on immuncity and safety and not a large lone trial based on events. So we think we can complete that fast. And if anyone can do it first, it's we. So that's very high on our list currently pending data to move with light speed.

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

Right. And there was a question on reinvestment of Pfizer, Chris, I think.

Christopher J. Stevo - Pfizer Inc. - Senior VP & Chief IR Officer

Yes. I think, Kerry, you asked if the second season durability data, how that will impact reimbursement discussions, so if we submitted [mature].

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

Yes. I think it will impact ACIP recommendation in vaccines. Once you have ACIP recommendation or not, you're getting automatic actions with all formularies without co-pay. So that, I think it will be the key what ACIP will say.

Operator

Our next question will come from Andrew Baum with Citi.

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

On PAXLOVID, following commercial approval and the withdrawal of the EUA, will pharmacist prescribing remain intact? And then a couple for Mikael. Could you just explain the reasons for the out-licensing of the TL1A inhibitor to Roivant? I apologize if I missed it. And then second, in relation to your multispecific antibodies or trispecifics, this has been tried previously. I think AbbVie and J&J previously tried in RA and I think in psoriasis with TNF IL-17, but they ran into an issue with binding affinity and they didn't have efficacy. Do you think you've managed to solve the issue here?

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

Andrew, the first one is simple, I don't know, in the pharmacist group. It's very likely, I think. But I don't know, we don't have it in our assumptions right now. And let's go to Mikael.

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

I'll start with, Andrew, great question. You touched my heart today. We have cracked it. These antibodies that I shared today have, first of all, pharmacokinetics like an excellent single antibody but 3-in-1 product and have very high potency, which you asked about, actually exceeding the marketed product substantially. So we think it's really something that we will move very quickly as we learn more of it.

And you asked about TL1A. We think we have a very good partnership with Roivant that helps us to do more things within our pipeline. And you have heard Aamir Malik earlier alluded to that we have commercialization rights ex U.S., Japan. We have about half of the value of this product. And we have a follow-on bispecific TL1A [before that sets a] active mechanism STELARA. So we think we have such a richness in this space and really enjoy to build the ecosystem with others and maximize what we bring to patients.

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

Aamir, you want to add something here?

Aamir Malik - Pfizer Inc. - Executive VP & Chief Business Innovation Officer

The only quick thing I will add, Andrew, is if you look at how prolific our R&D engine has been, the total funding demand from all of the R&D programs that were generated would significantly exceed what we guided to as our R&D spending in '22 and '23. So in that context, we are going to be very thoughtful about how we prioritize. We have a robust process for that.

And consequently, from time to time, you're going to see programs like the TL1A that have very clear scientific merit, but we think we're sharing the cost, the risk and capabilities with the partner is the best way to create value. And that's what we did in that situation. And we've had a long history of doing that in a number of other situations as well.

Operator

Our last question will come from Evan Seigerman with BMO.

Evan David Seigerman - BMO Capital Markets Equity Research - MD & Senior BioPharma Research Analyst

And I'm not going to ask a COVID question because I think they were all asked. So just looking at business development, when you did Biohaven, what were some of the characteristics of the deal that you want to bring forward in kind of your go-forward approach for BD? How should we think about potential holes in your pipeline that you could fill with external deals?

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

Aamir, why don't you take this one?

Aamir Malik - Pfizer Inc. - Executive VP & Chief Business Innovation Officer

Sure. The Biohaven deal for us represented an excellent opportunity to leverage our capabilities. And specifically, where were capabilities in terms of our global commercial footprint, that Biohaven as a company alone could not maximize but where application of those capabilities could take Nurtec and the follow-on product to places and reach us for patients that they couldn't have gotten to alone. And also the way in which we structured that transaction, began with an ex U.S. partnership, which we then expanded to take on this full global CGRP franchise and also excluded some assets that were less relevant to us strategically that created a NewCo.

And I think what you can take away from that is that we're going to continue to look for things that are scientific breakthroughs where we can add capabilities, and we're also going to be creative and disciplined about how we structure our deals. And we think that's going to serve us well as we complete our ambition against our \$25 billion goal.

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

Thank you, Aamir. So thank you, operator. In summary, let me close by saying, first of all, I feel extremely proud for the team in Pfizer that was able to deliver, break all records in 2022, the highest-ever revenue, the highest-ever profits, the highest, more important ever number of patients that we protected or treated with our medicines, the best-ever reputation for our company, the most productive wave of R&D with 18 -- 19 products launching in the next 18 months, the best R&D machine in terms of multiple measures. All of that, we're able to achieve in 2022.

Clearly though, I believe that the best years of Pfizer are ahead because we are building on a significant capital position, but we know how to deploy to create growth. We are building on an R&D engine, that it is more productive than ever in the history of this company. A manufacturing engine that it is the envy of the industry. A commercial engine -- a commercial engine that it is around again and again and again as the best commercial engine in the industry.

And, of course, a mindset in Pfizer that is characterized but nothing is impossible. We can make everything possible. So with that in mind, I think that we are moving ahead, hopefully, to an even more successful 2023. Thank you very much for your attention, your interest in us and your support as shareholders.

Operator

Thank you, ladies and gentlemen. This does conclude Pfizer's Fourth Quarter 2022 Earnings Conference Call. We appreciate your participation, and you may disconnect your line at any time.

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