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PFIZER REPORTS THIRD-QUARTER 2021 RESULTS

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- Third-Quarter 2021 Revenues of $24.1 Billion, Reflecting 130% Operational Growth; Excluding Comirnaty(1), Revenues Grew 7% Operationally to $11.1 Billion
- Third-Quarter 2021 Reported Diluted EPS(2) of $1.42, Adjusted Diluted EPS(3) of $1.34
- Raises Full-Year 2021 Guidance(4) for Revenues to a Range of $81.0 to $82.0 Billion and Adjusted Diluted EPS(3) to a Range of $4.13 to $4.18, Reflecting 94% and 84% Year-Over-Year Growth at the Midpoints, Respectively
    - Anticipates 2021 Revenues of Approximately $36 Billion for Comirnaty(1), Reflecting 2.3 Billion Doses Expected to be Delivered in Fiscal 2021
    - Raises Midpoint of Guidance for Adjusted Diluted EPS(3) Excluding Comirnaty(1) to a Range of $2.60 to $2.65
- Will Highlight Promising New Data on Multiple Novel Compounds in I&I, as Well as Clinical and Regulatory Updates for Gene Therapy and COVID-19 Development Programs on Conference Call

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) reported financial results for third-quarter 2021 and raised 2021 guidance(4) for revenues and Adjusted diluted EPS(3) reflecting the net impact of its updated expectations for contributions to 2021 performance from both Comirnaty(1), the Pfizer-BioNTech SE (BioNTech) COVID-19 vaccine, as well as its business excluding Comirnaty(1).

Additionally, Pfizer published this morning on its website the third-quarter 2021 earnings presentation and accompanying prepared remarks from management as well as the quarterly update to its R&D pipeline.

EXECUTIVE COMMENTARY

Dr. Albert Bourla, Chairman and Chief Executive Officer, stated: “While we are proud of our third quarter financial performance, we are even more proud of what these financial results represent in terms of the positive impact we are having on human lives around the world. For example, more than 75% of the revenues we have recorded up through third-quarter 2021 for Comirnaty(1) have come from supplying countries outside the U.S., and we remain on track to achieve our goal of delivering at least two billion doses to low- and middle-income countries by the end of 2022 -- at least one billion to be delivered this year and one billion next year, with the possibility to increase those deliveries if more orders are placed by these countries for 2022. One billion of these doses will be supplied to the U.S. government at a not-for-profit price to be donated to the world’s poorest nations at no charge to those countries. Despite all we have been able to accomplish to date, we remain focused on our future, not our past. Our ultimate goal is to help bring this pandemic to an end as quickly as possible, but also to apply the lessons we have learned through our work on the vaccine to all of our therapeutic areas. We look forward to providing future updates on these efforts.”

Frank D’Amelio, Chief Financial Officer and Executive Vice President, Global Supply, stated: “I continue to be very pleased with the way our business is performing in 2021, both including and excluding the significant contributions of Comirnaty(1) to our results. In addition to raising our expectations for revenues and Adjusted

diluted EPS[3] for the company including Comirnaty[1], today we are also increasing the midpoint of our guidance range for Adjusted diluted EPS[3] excluding Comirnaty[1] for the second consecutive quarter, demonstrating our ability to execute on our broader strategies beyond the vaccine. We continue to make progress on advancing our internal pipeline across all therapeutic areas while also prudently deploying our capital through partnerships and bolt-on acquisitions to gain access to cutting-edge platforms, science and technologies that could potentially bolster our growth in the latter half of this decade. I am proud of what we have accomplished so far in 2021 and look forward to finishing the year strong."

Results for the third quarter and the first nine months of 2021 and 2020[5] are summarized below.

OVERALL RESULTS

($ in millions, except per share amounts)	Third-Quarter			Nine Months		
	2021	2020	Change	2021	2020	Change
Revenues	$24,094	$10,277	134%	$57,653	$30,224	91%
Reported Net Income[2]	8,146	1,469	*	18,586	8,313	*
Reported Diluted EPS[2]	1.42	0.26	*	3.27	1.48	*
Adjusted Income[3]	7,687	3,303	133%	19,033	10,322	84%
Adjusted Diluted EPS[3]	1.34	0.59	129%	3.35	1.84	82%

* Indicates calculation not meaningful.

REVENUES

($ in millions)	Third-Quarter				Nine Months			
	2021	2020	% Change		2021	2020	% Change	
			Total	Oper.			Total	Oper.
Vaccines	$ 14,583	$ 1,717	*	*	$ 28,711	$ 4,574	*	*
Oncology	3,085	2,761	12%	11%	9,091	7,843	16%	14%
Internal Medicine	2,097	2,085	1%	(1%)	7,093	6,695	6%	4%
Hospital	2,367	1,790	32%	29%	6,968	5,741	21%	18%
Inflammation & Immunology	1,094	1,173	(7%)	(7%)	3,200	3,299	(3%)	(5%)
Rare Disease	869	752	16%	15%	2,588	2,071	25%	22%
Total Revenue	**$ 24,094**	**$ 10,277**	**134%**	**130%**	**$ 57,653**	**$ 30,224**	**91%**	**86%**

* Indicates calculation not meaningful.

Following the completion of the spin-off of the Upjohn Business[6] in the fourth quarter of 2020, Pfizer operates as a focused innovative biopharmaceutical company engaged in the discovery, development, manufacturing, marketing, sale and distribution of biopharmaceutical products worldwide.

Revenues and expenses associated with the Upjohn Business[6] for all prior year periods presented have been recategorized as discontinued operations and excluded from Adjusted[3] results. Pfizer's Meridian subsidiary, the manufacturer of EpiPen and other auto-injector products, which had been reported within the results of the Upjohn Business[6] in the first three quarters of 2020, is included within the Hospital therapeutic area for all periods presented.

Business development activities completed in 2020 and 2021 impacted financial results in the periods presented [6]. Some amounts in this press release may not add due to rounding. All percentages have been calculated using unrounded amounts. References to operational variances pertain to period-over-period changes that exclude the impact of foreign exchange rates[7].

2021 FINANCIAL GUIDANCE[4]

Financial guidance reflects management's current expectations for operational performance, foreign exchange rates and management's current projections as to the severity, duration and global macroeconomic impact of the COVID-19 pandemic.

Pfizer is raising 2021 total company guidance for revenues and Adjusted diluted EPS[3]. This reflects the net impact of its updated outlook for contributions to 2021 performance from both Comirnaty[1] and its business excluding Comirnaty[1]. The guidance range for Adjusted[3] R&D expenses was increased primarily to reflect anticipated incremental spending on COVID-19 and mRNA-based projects. Ranges for various other components of financial guidance were tightened within their previous ranges primarily to reflect the passage of time and actual performance to date. Current 2021 financial guidance is presented below.

Revenues	$81.0 to $82.0 billion *(previously $78.0 to $80.0 billion)*
Adjusted Cost of Sales[3] as a Percentage of Revenues	39.1% to 39.6% *(previously 39.0% to 40.0%)*
Adjusted SI&A Expenses[3]	$11.6 to $12.1 billion *(previously $11.5 to $12.5 billion)*
Adjusted R&D Expenses[3]	$10.4 to $10.9 billion *(previously $10.0 to $10.5 billion)*
Adjusted Other (Income)/Deductions[3]	Approximately $2.3 billion of income *(previously approximately $2.2 billion of income)*
Effective Tax Rate on Adjusted Income[3]	Approximately 16.0%
Adjusted Diluted EPS[3]	$4.13 to $4.18 *(previously $3.95 to $4.05)*

The midpoint of the guidance range for revenues represents 94% growth from 2020 revenues, including an expected $1.3 billion, or 3%, favorable impact from changes in foreign exchange rates compared to 2020. The midpoint of the updated guidance range for Adjusted diluted EPS(3) reflects an 84% increase over 2020 actual results(8), including an expected $0.09, or 4%, benefit due to favorable changes in foreign exchange rates compared to 2020.

Financial guidance for Adjusted diluted EPS(3) is calculated using approximately 5.7 billion weighted average shares outstanding, and continues to assume no share repurchases in 2021.

Update to Assumptions Related to Comirnaty(1) Within 2021 Guidance

Due to additional supply agreements that have been signed since mid-July, Pfizer is updating the revenue assumptions related to Comirnaty(1) incorporated within the above guidance ranges. The updated assumptions are summarized below.

Revenues for Comirnaty(1)	Approximately $36 billion *(previously approximately $33.5 billion)*
Adjusted Income(3) Before Tax (IBT) Margin for Comirnaty(1)	High-20s as a Percentage of Revenues

The Comirnaty(1) revenue projection incorporated within Pfizer's 2021 financial guidance includes approximately 2.3 billion doses that are expected to be delivered in fiscal 2021(5) based on expected ordering patterns through the end of December for the U.S. and through the end of November for the rest of the world. Pfizer and BioNTech continue to expect to manufacture 3 billion doses in total by the end of December 2021. The difference between the number of doses expected to contribute to 2021 revenues versus the number of doses expected to be manufactured by year-end relates to anticipated international deliveries in December, which will be recorded as revenue in 2022 due to our international fiscal calendar(5), and, to a lesser extent, doses expected to be produced but not yet delivered as of December 31, 2021.

Adjusted(3) IBT margin guidance for Comirnaty(1) incorporates the expectation for revenues for the product, less anticipated Adjusted(3) costs to manufacture, market and distribute Comirnaty(1), including applicable royalty expenses, and a 50% gross profit split with BioNTech, as well as shared R&D expenses related to ongoing Comirnaty(1) development efforts and costs associated with other assets currently in development for the prevention and treatment of COVID-19. It also includes R&D expenses related to other mRNA-based development programs. It does not include an allocation of corporate or other overhead costs.

Selected Financial Guidance Ranges Excluding Comirnaty(1)

Pfizer is updating its financial guidance ranges for revenues and Adjusted diluted EPS(3) excluding contributions from Comirnaty(1). Both financial guidance components were tightened within their previous guidance ranges primarily to reflect the passage of time and actual performance to date. In addition, guidance for revenues excluding Comirnaty(1) was tightened around the lower end of the previous range as a result of the Chantix recall and pause in global shipments.

Revenues	$45.0 to $46.0 billion *(previously $45.0 to $47.0 billion)*
Adjusted Cost of Sales[3] as a Percentage of Revenues	21% to 22%
Adjusted Diluted EPS[3]	$2.60 to $2.65 *(previously $2.55 to $2.65)*

The midpoint of the revenue guidance range above reflects approximately 6% operational growth compared to 2020 when sales of Comirnaty[1] are excluded from both periods, which is in line with the company's stated goal of at least a 6% revenue compound annual growth rate through 2025. The midpoint of Pfizer's Adjusted diluted EPS[3] guidance range excluding Comirnaty[1] reflects approximately 12% operational growth compared to the prior year[8].

CAPITAL ALLOCATION

- During the first nine months of 2021, Pfizer paid $6.5 billion of cash dividends, or $1.17 per share of common stock, which represents an increase in dividends per share of 3% compared to the same period last year.
- No share repurchases have been completed to date in 2021. As of November 2, 2021, Pfizer's remaining share repurchase authorization is $5.3 billion. Current 2021 financial guidance does not reflect any share repurchases in 2021.
- Third-quarter 2021 diluted weighted-average shares outstanding used to calculate Reported[2] and Adjusted[3] diluted EPS was 5,725 million shares, an increase of 92 million shares, primarily due to shares issued for employee compensation programs, which resulted in a $0.02 reduction to both Reported[2] and Adjusted[3] diluted EPS compared to the prior-year quarter.

QUARTERLY FINANCIAL HIGHLIGHTS (Third-Quarter 2021 vs. Third-Quarter 2020)

Third-quarter 2021 revenues totaled $24.1 billion, an increase of $13.8 billion, or 134%, compared to the prior-year quarter, reflecting operational growth of $13.4 billion, or 130%, as well as a favorable impact of foreign exchange of $421 million, or 4%.

Third-quarter 2021 operational growth was primarily driven by:

- Comirnaty[1], which contributed $13.0 billion in direct sales and alliance revenues;
- Eliquis globally, up 19% operationally, driven primarily by continued increased adoption in non-valvular atrial fibrillation and oral anti-coagulant market share gains;
- Vyndaqel/Vyndamax, up 42% operationally, primarily driven by continued strong uptake of the transthyretin amyloid cardiomyopathy indication in the U.S., developed Europe and Japan;
- Inlyta globally, up 30% operationally, primarily reflecting continued adoption in the U.S. and developed Europe of combinations of certain immune checkpoint inhibitors and Inlyta for the first-line treatment of patients with advanced renal cell carcinoma;
- Xtandi in the U.S., up 16%, primarily driven by strong demand across the metastatic and non-metastatic castration-resistant prostate cancer indications and the metastatic castration-sensitive prostate cancer indication;
- Ibrance outside of the U.S., up 9% operationally, driven by accelerating demand as the delays in diagnosis and treatment initiations caused by COVID-19 show signs of recovery across several international

markets; as well as

- Hospital products globally, which grew 29% operationally to $2.4 billion, primarily driven by Pfizer CentreOne, Pfizer's contract manufacturing operation, reflecting certain Comirnaty-related manufacturing activities performed on behalf of BioNTech[(1)] and manufacturing of legacy Upjohn products for Viatris[(6)], as well as growth from international markets, primarily driven by the anti-infectives portfolio; and
- Biosimilars, which grew 34% operationally to $575 million, primarily driven by recent oncology monoclonal antibody biosimilar launches of Ruxience (rituximab), Zirabev (bevacizumab) and Trazimera (trastuzumab), as well as continued growth from Retacrit (epoetin) in the U.S.,

partially offset primarily by lower revenues for:

- Chantix globally, down 97% operationally, driven by the voluntary recall across multiple markets and the global pause in shipments of Chantix due to the presence of N-nitroso-varenicline above an acceptable level of intake set by various global regulators, the ultimate timing for resolution of which may vary by country;
- Prevnar family (Prevnar/Prevenar 13 & 20) globally, down 7% operationally, driven primarily by a 36% decline in the adult indication in the U.S. due to the ongoing prioritization of primary and booster vaccination campaigns for COVID-19 by U.S. health authorities and a later start to the flu season compared to the prior year, as well as the continued impact of the lower remaining unvaccinated eligible adult population and the June 2019 change to the Advisory Committee on Immunization Practices (ACIP) recommendation for the Prevnar 13 adult indication to shared clinical decision-making;
- Sutent globally, down 31% operationally, primarily reflecting lower volume demand in the U.S. resulting from its loss of exclusivity in August 2021;
- Xeljanz in the U.S., down 13%, reflecting the negative impact of a review by the U.S. Food and Drug Administration (FDA) which resulted in a Drug Safety Communication (DSC) related to Xeljanz and two competitors' arthritis medicines in the same drug class, as well as an unfavorable change in channel mix toward lower-priced channels and continued investments to improve formulary positioning and unlock access to additional patient lives; and
- Enbrel internationally, down 12% operationally, primarily reflecting continued biosimilar competition.

GAAP Reported[(2)] Income Statement Highlights

SELECTED REPORTED COSTS AND EXPENSES[(2)]

($ in millions)	Third-Quarter				Nine Months			
			% Change				% Change	
	2021	2020	Total	Oper.	2021	2020	Total	Oper.
Cost of Sales[(2)]	$ 9,973	$2,007	*	*	$ 21,232	$ 5,773	*	*
Percent of Revenues	41.4%	19.5%	N/A	N/A	36.8%	19.1%	N/A	N/A
SI&A Expenses[(2)]	2,905	2,658	9%	8%	8,617	7,858	10%	8%
R&D Expenses[(2)]	3,447	2,300	50%	49%	7,920	6,050	31%	30%
Total	**$16,326**	**$6,965**	*	*	**$ 37,770**	**$ 19,681**	**92%**	**87%**
Other (Income)/Deductions—net[(2)]	($1,696)	$1,878	*	*	($3,697)	$1,114	*	*

Effective Tax Rate on Reported Income[2]	(4.2%)	(60.9%)		7.5%	6.7%

* Indicates calculation not meaningful.

Third-quarter 2021 Cost of Sales[2] as a percentage of revenues increased 21.9 percentage points compared with the prior-year quarter. The drivers for the increase include, among other things:

- an increase of approximately 21 percentage points associated with sales of Comirnaty[1], which includes a charge for the 50% gross profit split with BioNTech and applicable royalty expenses; and
- unfavorable changes in product mix, reflecting higher sales of lower margin products including revenues from the Pfizer CentreOne operation and lower sales of Chantix, partially offset by the favorable impact of higher alliance revenues.

SI&A Expenses[2] increased 8% operationally in third-quarter 2021 compared with the prior-year quarter, primarily driven by incremental costs associated with the implementation of our cost-reduction and productivity initiatives, as well as increased product-related spending across multiple therapeutic areas and other costs associated with activity that is closer to pre-pandemic levels as compared to the prior-year quarter.

Third-quarter 2021 R&D Expenses[2] increased 49% operationally compared with the prior-year quarter, which primarily reflects a $650 million up-front payment related to the global collaboration agreement with Arvinas, Inc. to develop and commercialize ARV-471 and increased investments across multiple therapeutic areas, including additional spending related to the development and at-risk manufacturing of the COVID-19 anti-viral programs.

Pfizer recorded $1.7 billion of other income—net[2] in third-quarter 2021 compared with $1.9 billion of other deductions—net[2] in third-quarter 2020. The period-over-period change was primarily driven by:

- net periodic benefit credits recorded in third-quarter 2021 versus net periodic benefit costs recorded in the prior-year quarter, primarily resulting from pension plan interim actuarial remeasurement gains and losses, respectively[8];
- the non-recurrence of certain asset impairment charges that were incurred in third-quarter 2020; and
- net gains on equity securities in third-quarter 2021 versus net losses on equity securities recognized in the prior-year quarter.

Pfizer's effective tax rate on Reported income[2] for third-quarter 2021 was negative, primarily as a result of certain initiatives executed in third-quarter 2021 associated with Pfizer's investment in the Consumer Healthcare joint venture with GlaxoSmithKline plc (GSK).

Adjusted[3] Income Statement Highlights

SELECTED ADJUSTED COSTS AND EXPENSES[3]

($ in millions)	Third-Quarter			Nine Months		
	2021	2020	% Change Oper.	2021	2020	% Change Oper.

Adjusted Cost of Sales[3]	$	9,937	$	1,989	*	$	21,112	$	5,701	*
Percent of Revenues		41.2%		19.1%			36.6%		18.9%	
Adjusted SI&A Expenses[3]		2,732		2,562	7%		8,183		7,540	9%
Adjusted R&D Expenses[3]		2,740		2,298	19%		7,026		5,812	21%
Total	**$**	**15,409**	**$**	**6,849**	*	**$**	**36,320**	**$**	**19,053**	91%
Adjusted Other (Income)/Deductions—net[3]		($569)		($394)	44%		($1,744)		($1,166)	50%
Effective Tax Rate on Adjusted Income[3]		15.3%		11.8%			15.7%		14.2%	

* Indicates calculation not meaningful.

A full reconciliation of Reported[2] to Adjusted[3] financial measures and associated footnotes can be found in the financial tables section of the press release located at the hyperlink below.

RECENT NOTABLE DEVELOPMENTS (Since July 28, 2021)

Product Developments

- **Abrilada (adalimumab-afzb, biosimilar)** -- In September 2021, Pfizer received positive topline results from the REFLECTIONS B538-12 study which evaluated multiple switches between treatment with Abrilada and its reference product, Humira®, both of which were administered with methotrexate in adult patients living with moderate to severe rheumatoid arthritis (RA). The study met its primary endpoint by demonstrating pharmacokinetic equivalence in patients who switched multiple times between treatment with the two medicines. Safety and immunogenicity were similar between both arms. Pfizer plans to launch citrate-free Abrilada in the U.S. as early as July 1, 2023 in accordance with the terms of agreement with the originator company.
- **Chantix (varenicline)** -- In September 2021, Pfizer voluntarily recalled all lots of Chantix in the U.S. due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit. Nitrosamines are common in water and foods and everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. The health benefits of stopping smoking outweigh the theoretical potential cancer risk from the nitrosamine impurity in varenicline.
- **Cibinqo (abrocitinib)**
  - In August 2021, Pfizer announced that JADE DARE (B7451050), a 26-week, randomized, double-blind, double-dummy, active-controlled, multi-center Phase 3 study evaluating abrocitinib 200 mg head-to-head with dupilumab 300 mg in adult patients on background topical therapy with moderate to severe atopic dermatitis (AD), met its co-primary and key secondary efficacy endpoints. The study showed that abrocitinib was statistically superior compared to dupilumab in each evaluated efficacy measure and had a safety profile consistent with previous studies.
  - In September 2021, Pfizer announced that the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for Cibinqo for the treatment of moderate to severe AD in adults and adolescents aged 12 years and older, who are candidates for systemic therapy. Cibinqo is licensed in Great Britain in recommended doses of 100 mg and 200 mg.
  - In September 2021, Pfizer announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) approved Cibinqo for the treatment of moderate to severe AD in adults and adolescents aged 12 years and older, with inadequate response to existing therapies. Cibinqo will be available in Japan in doses of 100 mg and 200 mg.

- In October 2021, Pfizer announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the 100 mg and 200 mg doses of abrocitinib for marketing authorization to treat moderate to severe AD in adults who are candidates for systemic therapy.

- **Comirnaty (BNT162b2, COVID-19 Vaccine, mRNA)**
  - **Clinical and Research Developments**
    - In September 2021, Pfizer and BioNTech announced results from a Phase 2/3 trial of BNT162b2 showing a favorable safety profile and robust neutralizing antibody responses in children 5 through 11 years of age using a two-dose regimen of 10 µg administered 21 days apart, a smaller dose than the 30 µg dose used for people 12 and older. The antibody responses in the participants given 10 µg doses were comparable to those recorded in a previous Pfizer-BioNTech study in people 16 to 25 years of age immunized with 30 µg doses. The 10 µg dose was selected as the preferred dose for safety, tolerability and immunogenicity in children 5 through 11 years of age.
    - In October 2021, Pfizer and BioNTech announced topline results from a Phase 3 randomized, controlled trial evaluating the efficacy and safety of a 30 µg booster dose of Comirnaty in more than 10,000 individuals 16 years of age and older. In the trial, a booster dose administered to individuals who previously received the primary two-dose series of Comirnaty restored vaccine protection against COVID-19 to the high levels achieved after the second dose, showing a relative vaccine efficacy of 95.6% when compared to those who did not receive a booster. These are the first efficacy results from any randomized, controlled COVID-19 vaccine booster trial. The adverse event profile was generally consistent with other clinical safety data for the vaccine, with no new safety concerns identified.
  - **Regulatory Developments**
    - In August 2021, Pfizer and BioNTech announced that the FDA approved the Biologics License Application (BLA) for Comirnaty to prevent COVID-19 in individuals 16 years of age and older as a two-dose primary series (30 µg per dose) based on a comprehensive data package that included longer-term follow-up data from the Phase 3 trial, where the vaccine's high efficacy and safety profile were observed up to six months after the second dose. Comirnaty is the first COVID-19 vaccine to be granted approval by the FDA and had previously been available to this patient population in the U.S. under Emergency Use Authorization (EUA) since December 11, 2020. The vaccine remains available to individuals 12 to 15 years old under an EUA granted by the FDA on May 10, 2021[(9)].
    - In August 2021, Pfizer and BioNTech announced the initiation of a supplemental Biologics License Application (sBLA) to the FDA for the approval of a booster (third) dose of Comirnaty to prevent COVID-19 in individuals 16 years of age and older. The sBLA includes data from a Phase 3 clinical trial of 306 participants 18-55 years of age who received a third dose of Comirnaty between 4.8 and 8 months after completing the two-dose primary regimen, with a median follow-up time of 2.6 months post-booster. SARS-CoV-2 50% neutralizing titers after the third dose were 3.3 times the titers after the second dose. The frequency of reactogenicity was similar to or better than after dose two of the primary series. The adverse event profile was generally consistent with other clinical data for Comirnaty.
    - In September 2021, Pfizer and BioNTech announced that the FDA authorized for emergency use[(9)] a booster dose of Comirnaty for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. The booster dose is to be administered at least six months after completion of the primary series and is the same formulation and dosage strength as the doses in the primary series. In addition, in October 2021, the FDA authorized for emergency use[(9)] a booster dose to eligible individuals who

have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing intervals for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.
    - In October 2021, the EU Conditional Marketing Authorisation (CMA) for Comirnaty was updated to include the administration of Comirnaty as a 30 µg booster dose at least six months after the second dose in individuals 18 years of age and older. The decision is applicable to all 27 EU member states.
    - In October 2021, Pfizer and BioNTech announced that the FDA has authorized BNT162b2 for emergency use[9] for children 5 through 11 years of age. For this group, the vaccine is to be administered in a two-dose regimen of 10 µg doses given 21 days apart. The FDA based its decision on data from a Phase 2/3 randomized, controlled trial that included ~4,500 participants (2,268 from the original group and 2,379 from the supplemental safety group). Results from this trial were reviewed by the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC), which voted 17 to 0, with 1 abstention, to recommend that the FDA grant an EUA for the vaccine in this age group. As a next step, the U.S. Centers for Disease Control and Prevention's (CDC) ACIP will meet to discuss a potential recommendation for the use and rollout of the vaccine to children 5 through 11 years of age. The companies have submitted requests for authorization in this age group to other regulators around the world, including the EMA.
  - **Commercial Developments**
    - In August 2021, Pfizer and BioNTech announced the signing of a letter of intent with Eurofarma Laborat?rios SA, a Brazilian biopharmaceutical company, to manufacture Comirnaty for distribution exclusively within Latin America. Per the agreement, Eurofarma will obtain drug product from facilities in the U.S. and manufacturing of finished doses will commence in 2022. At full operational capacity, production is expected to exceed 100 million finished doses annually.
    - In September 2021, Pfizer and BioNTech announced plans to expand their agreement with the U.S. government by providing an additional 500 million doses of Comirnaty at a not-for-profit price for donation to low- and lower-middle-income countries and the organizations that support them. This expanded agreement brings the total of doses to be supplied to the U.S. government for donation to these countries to 1 billion. Deliveries of the initial doses began in August 2021, and the total 1 billion doses are expected to be delivered by the end of September 2022.
    - In October 2021, Pfizer and BioNTech announced that the U.S. government exercised its final purchase option under the existing U.S. supply agreement to purchase 50 million additional doses of BNT162b2. These additional doses are intended to support U.S. preparedness for pediatric vaccinations, including securing vaccines for children under 5 years of age, should they receive regulatory authorization. This brings the total number of doses that are now secured under the agreement to 600 million, spanning doses for adults, adolescents and children. The companies expect to deliver all these doses by April 30, 2022.
- **Eliquis (apixaban)** -- In September 2021, the Bristol-Myers Squibb-Pfizer Alliance announced that the U.S. Court of Appeals for the Federal Circuit affirmed the U.S. District Court's August 2020 decision finding the composition of matter patent (US 6,967,208) and formulation patent (US 9,326,945) covering Eliquis valid and infringed. With this decision, the earliest that generic manufacturers are permitted to launch their apixaban products is April 1, 2028, subject to additional appeals and challenges.
- **Myfembree (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg)** -- In September 2021, Myovant Sciences (Myovant) and Pfizer announced that the FDA accepted for review a supplemental New Drug Application (sNDA) for Myfembree for the management of moderate to severe pain associated with endometriosis. The Prescription Drug User Fee Act (PDUFA) goal date for a decision

by the FDA is in May 2022.

- **Prevnar 20 (pneumococcal 20-valent conjugate vaccine)**
    - In September 2021, Pfizer announced positive top-line results from a Phase 3 study evaluating the safety and immunogenicity of Prevnar 20 in adults 65 years of age or older when administered at the same time as the seasonal influenza vaccine (SIIV, Fluad Quadrivalent [adjuvanted], 2020/2021 strains). Responses elicited by Prevnar 20 for all 20 serotypes and by seasonal influenza vaccine when given together were noninferior (the study's primary immunogenicity objectives) to those elicited by the vaccines when administered one month apart. The safety profile of Prevnar 20 was similar when the vaccines were coadministered as compared to when each vaccine was administered separately, one month apart.
    - In October 2021, Pfizer announced that the CDC's ACIP voted to recommend Prevnar 20 for routine use to help protect adults against invasive disease and pneumonia caused by the 20 *Streptococcus pneumoniae* serotypes in the vaccine. The ACIP recommended that adults 65 years of age or older and adults aged 19 years of age or older with certain underlying medical conditions or other risk factors should receive a pneumococcal conjugate vaccine (either Prevnar 20 or PCV15) if they have not previously received a pneumococcal conjugate vaccine or if their previous vaccination history is unknown. If PCV15 is used, this should be followed by a dose of PPSV23.
- **TicoVac (tick-borne encephalitis vaccine)** -- In August 2021, Pfizer announced that the FDA approved TicoVac for active immunization to prevent tick-born encephalitis (TBE) in individuals 1 year of age and older. TicoVac is the only FDA-approved vaccine to help protect U.S. adults and children against TBE virus when visiting or living in TBE endemic areas.
- **Xeljanz (tofacitinib)**
    - In August 2021, Pfizer announced that the European Commission (EC) approved Xeljanz for the treatment of active polyarticular juvenile idiopathic arthritis (JIA) and juvenile psoriatic arthritis (PsA) in patients two years of age and older who have responded inadequately to previous therapy with disease modifying antirheumatic drugs. Two formulations were approved, a tablet and a new oral solution (weight-based dosing). Xeljanz is the first and only Janus kinase (JAK) inhibitor approved in Europe for the treatment of polyarticular JIA and juvenile PsA and has received regulatory approval in four indications in the EU, the most of any JAK inhibitor.
    - In September 2021, the FDA issued a DSC related to Xeljanz/Xeljanz XR and two other arthritis medicines in the same drug class, based on its completed review of the ORAL Surveillance trial. The DSC stated that the FDA will require revisions to the Boxed Warnings for each of these medicines to include information about the risks of serious heart-related events, cancer, blood clots, and death. In addition, the DSC indicates the FDA's intention to limit approved uses of these products to certain patients who have not responded or cannot tolerate one or more tumor necrosis factor (TNF) blockers.
    - In October 2021, Pfizer announced that the CHMP of the EMA adopted a positive opinion recommending an extension to the existing indications for Xeljanz to include the treatment of adults with active ankylosing spondylitis who have responded inadequately to conventional therapy.
- **Xtandi (enzalutamide)** -- In September 2021, Astellas Pharma Inc. and Pfizer announced that Xtandi plus androgen deprivation therapy (ADT) reduced the risk of death by 34% compared to placebo plus ADT in the Phase 3 ARCHES study in men with metastatic hormone-sensitive prostate cancer (mHSPC), also known as metastatic castration-sensitive prostate cancer (mCSPC). Overall survival was a key secondary endpoint in the study. Primary results from ARCHES were published in the *Journal of Clinical Oncology* in 2019.

Pipeline Developments

A comprehensive update of Pfizer's development pipeline was published today and is now available at www.pfizer.com/science/drug-product-pipeline. It includes an overview of Pfizer's research and a list of compounds in development with targeted indication and phase of development, as well as mechanism of action for some candidates in Phase 1 and all candidates from Phase 2 through registration.

- **PF-06928316 (Respiratory Syncytial Virus (RSV) Vaccine Candidate)** -- In September 2021, Pfizer announced the initiation of RENOIR (RSV vaccine Efficacy study iN Older adults Immunized against RSV disease), a global, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy, immunogenicity, and safety of a single dose of its RSV bivalent prefusion F subunit investigational vaccine candidate (RSVpreF) in adults ages 60 years or older. The Phase 3 trial expects to enroll approximately 30,000 participants; the primary objectives of the study will assess safety and efficacy for the prevention of moderate to severe lower respiratory tract illness (msLRTI-RSV) during the first RSV season.
- **PF-07252220 (Influenza mRNA Vaccine)** -- In September 2021, Pfizer announced that the first participants were dosed in a Phase 1 clinical trial to evaluate the safety, tolerability and immunogenicity of a single dose quadrivalent mRNA vaccine against influenza in healthy adults. The influenza vaccine program is the first in a planned wave of Pfizer investigational programs leveraging mRNA technology for Pfizer.
- **PF-07304814 (Intravenous Protease Inhibitor for COVID-19)** -- As part of the National Institutes of Health's (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)-3 program, the National Institute of Allergy and Infectious Diseases is conducting a clinical trial to evaluate PF-07304814 in adults hospitalized with COVID-19. The trial initiated in September 2021, and the first participants in the clinical trial have now been dosed with PF-07304814 or placebo.
- **PF-07321332 (Oral Protease Inhibitor for COVID-19)**
    - In August 2021, Pfizer dosed the first participant in EPIC-SR (Evaluation of Protease Inhibition for COVID-19 in Standard-Risk patients), a pivotal Phase 2/3 clinical trial to evaluate the safety and efficacy of PF-07321332/ritonavir in non-hospitalized, symptomatic adult participants who have a confirmed diagnosis of SARS-CoV-2 infection and are not at increased risk of progressing to severe illness, which may lead to hospitalization or death. The randomized, double-blind trial will enroll approximately 1,140 participants, who will receive PF-07321332/ritonavir or placebo orally every 12 hours for five days.
    - In September 2021, Pfizer announced the start of the pivotal Phase 2/3 EPIC-PEP (Evaluation of Protease Inhibition for COVID-19 in Post-Exposure Prophylaxis) study to evaluate PF-07321332, co-administered with a low dose of ritonavir, for the prevention of COVID-19 infection. The randomized, double-blind, placebo-controlled trial will enroll up to 2,660 healthy individuals who are at least 18 years old and live in the same household as an individual with a confirmed symptomatic SARS-CoV-2 infection.
- **Ritlecitinib (PF-06651600)** -- In August 2021, Pfizer announced positive top-line results from the Phase 2b/3 ALLEGRO trial evaluating oral once-daily ritlecitinib in patients with alopecia areata, an autoimmune disease driven by an immune attack on the hair follicles that causes hair loss on the scalp and can also affect the face and body. Ritlecitinib 50 mg and 30 mg achieved the primary efficacy endpoint of the proportion of patients with less than or equal to 20% scalp hair loss after six months of treatment versus placebo.
- **Somatrogon (MOD-4023)** -- In September 2021, Pfizer and OPKO Health Inc. announced that the FDA has extended the review period for the BLA for somatrogon, a once-weekly long-acting recombinant human growth hormone, for the treatment of growth hormone deficiency in pediatric patients. The PDUFA goal date has been extended by three months to January 2022, as a result of Pfizer's submission of additional data to the original BLA.

- **Tanezumab (PF-04383119)** -- In October 2021, Pfizer and Eli Lilly and Company discontinued the global clinical development program for tanezumab, an investigational nerve growth factor (NGF) inhibitor. This decision was made following receipt of a Complete Response Letter (CRL) from the FDA for the tanezumab application in osteoarthritis (OA) and a negative opinion adopted by the EMA's CHMP on the tanezumab marketing authorization application in OA.
- **VLA15 (Lyme Disease Vaccine Candidate)** -- In September 2021, Valneva SE (Valneva) and Pfizer announced further positive Phase 2 results, including booster response, for their Lyme disease vaccine candidate from the VLA15-202 study. The two companies are working closely together on the next development steps and are planning for a Phase 3 trial starting in 2022. Pfizer plans to take over responsibility from Valneva for the Investigational New Drug Application (IND) with the FDA for VLA15 on November 15, 2021.
- **VTX-801 (Wilson Disease Gene Therapy)** -- In August 2021, Vivet Therapeutics (Vivet) and Pfizer announced that the FDA granted Fast Track designation to VTX-801, Vivet's novel investigational gene therapy for the treatment of Wilson Disease. Pfizer is collaborating with Vivet on the clinical supply of VTX-801 for the Phase 1/2 clinical trial in adult patients with Wilson Disease.

Corporate Developments

- In August 2021, Pfizer and Trillium Therapeutics Inc. (Trillium) announced that the companies entered into a definitive agreement under which Pfizer will acquire Trillium, a clinical stage immuno-oncology company developing innovative therapies for the treatment of cancer. Under the terms of the agreement, Pfizer will acquire all outstanding shares of Trillium not already owned by Pfizer for $18.50 per share, in cash, or an aggregate purchase price of approximately $2.26 billion. The proposed acquisition is expected to close in the fourth quarter of 2021 or first half of 2022, subject to customary closing conditions.
- In August 2021, Pfizer announced that Aamir Malik has joined the company as Executive Vice President and Chief Business Innovation Officer, reporting to Chairman and CEO Albert Bourla. Mr. Malik succeeds John Young, Executive Vice President and Chief Business Officer, who announced his intent to retire in early 2022 after a 34-year career at Pfizer.
- In November 2021, Pfizer entered into an agreement with Altaris Capital Partners, LLC (Altaris), a healthcare investment firm based in New York, for Altaris to purchase Meridian Medical Technologies (Meridian). Meridian was acquired by Pfizer in 2011 as part of the King Pharmaceuticals acquisition and has maintained relative operational autonomy since that time. Meridian's operations, which generate approximately $300 million in annual revenues, consist of manufacturing and distributing medical countermeasures used by the U.S. Department of Defense, Emergency Medical Services, Homeland Security and foreign ministries of health and defense, as well as rescue auto-injectors for the emergency treatment of allergic reactions including anaphylaxis. The transaction is expected to close in the coming months, subject to customary closing conditions including the receipt of regulatory approvals.

Please find Pfizer's press release and associated financial tables, including reconciliations of certain GAAP reported to non-GAAP adjusted information, at the following hyperlink:

https://investors.pfizer.com/files/doc_financials/2021/q3/Q3-2021-PFE-Earnings-Release.pdf

(Note: If clicking on the above link does not open up a new web page, you may need to cut and paste the above URL into your browser's address bar.)

For additional details, see the associated financial schedules and product revenue tables attached to the press release located at the hyperlink referred to above and the attached disclosure notice.

(1) Comirnaty includes direct sales and alliance revenues related to sales of the Pfizer-BioNTech SE (BioNTech) COVID-19 vaccine, which are recorded within Pfizer's Vaccines therapeutic area. It does not include revenues for certain Comirnaty-related manufacturing activities performed on behalf of BioNTech, which are included in the Pfizer CentreOne contract manufacturing operation within the Hospital area. Revenues related to these manufacturing activities totaled $187 million and $274 million for the third quarter and first nine months of 2021, respectively.

(2) Revenues is defined as revenues in accordance with U.S. generally accepted accounting principles (GAAP). Reported net income and its components are defined as net income attributable to Pfizer Inc. and its components in accordance with U.S. GAAP. Reported diluted earnings per share (EPS) is defined as diluted EPS attributable to Pfizer Inc. common shareholders in accordance with U.S. GAAP.

(3) Adjusted income and its components and Adjusted diluted EPS are defined as reported U.S. GAAP net income(2) and its components and reported diluted EPS(2) excluding purchase accounting adjustments, acquisition-related costs, discontinued operations and certain significant items (some of which may recur, such as actuarial gains and losses from pension and postretirement plan remeasurements, gains on the completion of joint venture transactions, restructuring charges, legal charges or gains and losses from equity securities, but which management does not believe are reflective of ongoing core operations). Adjusted cost of sales, Adjusted selling, informational and administrative (SI&A) expenses, Adjusted research and development (R&D) expenses and Adjusted other (income)/deductions are income statement line items prepared on the same basis as, and therefore components of, the overall Adjusted income measure.

As described in the *Non-GAAP Financial Measure: Adjusted Income* section of Management's Discussion and Analysis of Financial Condition and Results of Operations in Pfizer's 2020 Annual Report on Form 10-K, management uses Adjusted income, among other factors, to set performance goals and to measure the performance of the overall company. Because Adjusted income is an important internal measurement for Pfizer, management believes that investors' understanding of our performance is enhanced by disclosing this measure. Pfizer reports Adjusted income, certain components of Adjusted income, and Adjusted diluted EPS in order to present the results of the company's major operations—the discovery, development, manufacture, marketing, sale and distribution of prescription medicines and vaccines—prior to considering certain income statement elements. See the accompanying reconciliations of certain GAAP Reported to Non-GAAP Adjusted information for the third quarter and first nine months of 2021 and 2020. The Adjusted income and its components and Adjusted diluted EPS measures are not, and should not be viewed as, substitutes for U.S. GAAP net income and its components and diluted EPS(2).

(4) Pfizer does not provide guidance for GAAP Reported financial measures (other than revenues) or a reconciliation of forward-looking non-GAAP financial measures to the most directly comparable GAAP Reported financial measures on a forward-looking basis because it is unable to predict with reasonable certainty the ultimate outcome of pending litigation, unusual gains and losses, acquisition-related expenses, gains and losses from equity securities, actuarial gains and losses from pension and postretirement plan remeasurements and potential future asset impairments without unreasonable effort. These items are uncertain, depend on various factors, and could have a material impact on GAAP Reported results for the guidance period.

Financial guidance for full-year 2021 reflects the following:

- Does not assume the completion of any business development transactions not completed as of October 3, 2021, including any one-time upfront payments associated with such transactions.
- Includes Pfizer's pro rata share of the Consumer Healthcare joint venture anticipated earnings, which is recorded in Adjusted other (income)/deductions(3) on a one-quarter lag.

- Reflects an anticipated negative revenue impact of $0.6 billion due to recent and expected generic and biosimilar competition for certain products that have recently lost or are anticipated to soon lose patent protection.
- Reflects no sales of Chantix in the fourth quarter of 2021 as a result of a pause in global shipments of the product due to the presence of N-nitroso-varenicline above an acceptable level of intake set by various global regulators.
- Exchange rates assumed are a blend of actual rates in effect through third-quarter 2021 and mid-October 2021 rates for the remainder of the year. Financial guidance reflects the anticipated favorable impact of approximately $1.3 billion on revenues and approximately $0.09 on Adjusted diluted EPS(3) as a result of changes in foreign exchange rates relative to the U.S. dollar compared to foreign exchange rates from 2020.
- Guidance for Adjusted diluted EPS(3) assumes diluted weighted-average shares outstanding of approximately 5.7 billion shares, which assumes no share repurchases in 2021.
- Guidance for Adjusted other (income)/deductions(3) includes an estimated benefit of approximately $300 million resulting from a change in accounting principle to a more preferable policy under U.S. GAAP to immediately recognize actuarial gains and losses arising from the remeasurement of our pension and postretirement plans. This change went into effect in the first quarter of 2021 and prior period amounts have been recast to conform to the new accounting policy.

(5) Pfizer's fiscal year-end for international subsidiaries is November 30 while Pfizer's fiscal year-end for U.S. subsidiaries is December 31. Therefore, Pfizer's third quarter and first nine months for U.S. subsidiaries reflects the three and nine months ended on October 3, 2021 and September 27, 2020, while Pfizer's third quarter and first nine months for subsidiaries operating outside the U.S. reflects the three and nine months ended on August 29, 2021 and August 23, 2020.

(6) The following business development activity, among others, impacted financial results for the periods presented:

- On July 22, 2021, Arvinas Inc. (Arvinas) and Pfizer announced a global collaboration to develop and commercialize ARV-471, an investigational oral PROTAC® (PROteolysis TArgeting Chimera) estrogen receptor protein degrader. The estrogen receptor is a well-known disease driver in most breast cancers. Under the terms of the agreement, Pfizer paid Arvinas $650 million upfront. Separately, Pfizer made a $350 million equity investment in Arvinas. Arvinas is also eligible to receive up to $400 million in approval milestones and up to $1 billion in commercial milestones. The companies will equally share worldwide development costs, commercialization expenses and profits.
- On November 16, 2020, Pfizer completed the transaction to spin off its Upjohn Business and combine it with Mylan N.V. (Mylan) to form Viatris Inc. (Viatris). On December 21, 2020, which fell in Pfizer's international first-quarter 2021, Pfizer and Viatris completed the termination of a pre-existing strategic collaboration between Pfizer and Mylan for generic drugs in Japan (Mylan-Japan collaboration) and Pfizer transferred related operations that were part of the Mylan-Japan collaboration to Viatris. As a result of the spin-off of the Upjohn Business and the termination of the Mylan-Japan collaboration, the results of operations of the Upjohn Business and the Mylan-Japan collaboration are presented as discontinued operations.
- On April 9, 2020, Pfizer signed a global agreement with BioNTech to co-develop a first-in-class, mRNA-based coronavirus vaccine program, BNT162, aimed at preventing COVID-19 infection. In connection with the agreement, Pfizer paid BioNTech an upfront cash payment of $72 million in second-quarter 2020. Pfizer also made an equity investment of $113 million in BioNTech common stock. Pfizer made an additional investment of $50 million in common stock of BioNTech as part of an underwritten equity offering by BioNTech, which closed in July 2020. On January 29, 2021, Pfizer and BioNTech signed an

amended version of the April 2020 agreement. Under the January 2021 agreement, BioNTech paid Pfizer its 50 percent share of prior development costs in a lump sum payment during the first quarter of 2021. Further R&D costs are being shared equally.

(7) References to operational variances in this press release pertain to period-over-period growth rates that exclude the impact of foreign exchange rates. Although exchange rate changes are part of Pfizer's business, they are not within Pfizer's control and since they can mask positive or negative trends in the business, Pfizer believes presenting operational variances excluding these foreign exchange changes provides useful information to evaluate Pfizer's results.

(8) As described in footnote (4) above, in the first quarter of 2021, Pfizer adopted a change in accounting principle to a more preferable approach under U.S. GAAP related to its pension and postretirement plans. Prior period financial results have been recast to reflect this change. The recast comparable full-year 2020 Adjusted diluted EPS(3) is $2.26, versus $2.22 previously reported.

(9) Emergency uses of the Pfizer-BioNTech COVID-19 Vaccine have not been approved or licensed by the FDA, but have been authorized by the FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 5 years of age and older. COMIRNATY is licensed by the FDA for individuals 16 years of age and older. In addition, COMIRNATY is under EUA for individuals ages 12 through 15, a third dose for certain immunocompromised individuals 12 years of age and older, and a booster dose for certain individuals 18 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheet at www.cvdvaccine-us.com.

DISCLOSURE NOTICE: Except where otherwise noted, the information contained in this earnings release and the related attachments is as of November 2, 2021. We assume no obligation to update any forward-looking statements contained in this earnings release and the related attachments as a result of new information or future events or developments.

This earnings release and the related attachments contain forward-looking statements about, among other topics, our anticipated operating and financial performance; reorganizations; business plans and prospects; expectations for our product pipeline, in-line products and product candidates, including anticipated regulatory submissions, data read-outs, study starts, approvals, clinical trial results and other developing data, revenue contribution, growth, performance, timing of exclusivity and potential benefits; strategic reviews; capital allocation objectives; dividends and share repurchases; plans for and prospects of our acquisitions, dispositions and other business development activities, and our ability to successfully capitalize on these opportunities; manufacturing and product supply; our efforts to respond to COVID-19, including the Pfizer-BioNTech COVID-19 vaccine (Comirnaty) and our investigational protease inhibitors; and our expectations regarding the impact of COVID-19 on our business, operations and financial results that involve substantial risks and uncertainties. You can identify these statements by the fact that they use future dates or use words such as "will," "may," "could," "likely," "ongoing," "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "assume," "target," "forecast," "guidance," "goal," "objective," "aim," "seek" and other words and terms of similar meaning. Among the factors that could cause actual results to differ materially from past results and future plans and projected future results are the following:

Risks Related to Our Business, Industry and Operations, and Business Development:

- the outcome of R&D activities, including, the ability to meet anticipated pre-clinical or clinical endpoints, commencement and/or completion dates for our pre-clinical or clinical trials, regulatory submission dates,

and/or regulatory approval and/or launch dates; the possibility of unfavorable pre-clinical and clinical trial results, including the possibility of unfavorable new pre-clinical or clinical data and further analyses of existing pre-clinical or clinical data; the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; and whether and when additional data from our pipeline programs will be published in scientific journal publications and, if so, when and with what modifications and interpretations;

- our ability to successfully address comments received from regulatory authorities such as the FDA or the EMA, or obtain approval for new products and indications from regulators on a timely basis or at all; regulatory decisions impacting labeling, product dosage, manufacturing processes, safety and/or other matters, including decisions relating to emerging developments regarding potential product impurities; the impact of recommendations by technical or advisory committees; and the timing of pricing approvals and product launches;
- claims and concerns that may arise regarding the safety or efficacy of in-line products and product candidates, including claims and concerns that may arise from the outcome of post-approval clinical trials, which could impact marketing approval, product labeling, and/or availability or commercial potential, including uncertainties regarding the commercial or other impact of the results of the Xeljanz ORAL Surveillance (A3921133) study or any potential actions by regulatory authorities based on analysis of ORAL Surveillance or other data, including on other Janus kinase (JAK) inhibitors in our portfolio;
- the success and impact of external business-development activities, including the ability to identify and execute on potential business development opportunities; the ability to satisfy the conditions to closing of announced transactions in the anticipated time frame or at all; the ability to realize the anticipated benefits of any such transactions in the anticipated time frame or at all; the potential need for and impact of additional equity or debt financing to pursue these opportunities, which could result in increased leverage and/or a downgrade of our credit ratings; challenges integrating the businesses and operations; disruption to business and operations relationships; risks related to growing revenues for certain acquired products; significant transaction costs; and unknown liabilities;
- competition, including from new product entrants, in-line branded products, generic products, private label products, biosimilars and product candidates that treat diseases and conditions similar to those treated by our in-line products and product candidates;
- the ability to successfully market both new and existing products, including biosimilars;
- difficulties or delays in manufacturing, sales or marketing; supply disruptions, shortages or stock-outs at our or our third party suppliers' facilities; and legal or regulatory actions;

- the impact of public health outbreaks, epidemics or pandemics (such as the COVID-19 pandemic) on our business, operations and financial condition and results, including impacts on our employees, manufacturing, supply chain, sales and marketing, research and development and clinical trials;
- risks and uncertainties related to our efforts to develop and commercialize a vaccine to help prevent COVID-19 and potential treatments for COVID-19, as well as challenges related to their manufacturing, supply and distribution, including, among others, uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with pre-clinical and clinical data (including the Phase 2/3 data for Comirnaty), including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies or in larger, more diverse populations following commercialization; the ability of Comirnaty to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety or other developments,

including the risk of additional adverse reactions, some of which may be serious; the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program, potential treatments for COVID-19 or other programs will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future pre-clinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for Comirnaty in pediatric populations, applications for a potential booster dose and/or biologics license and/or EUA applications or amendments to any such applications may be filed in particular jurisdictions for Comirnaty or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such EUA or licenses will expire or terminate; whether and when any drug applications and/or EUA applications for any potential indications for any potential treatments for COVID-19 may be filed in any jurisdictions; whether and when any applications that may be pending or filed for Comirnaty (including the potential submissions for pediatric populations, a potential booster dose or any other requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program or potential treatments for COVID-19 may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's or drug's benefits outweigh its known risks and determination of the vaccine's or drug's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine or drug, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers, including our relationship with BioNTech; the risk that other companies may produce superior or competitive products; the risk that demand for any products may be reduced or no longer exist; risks related to the availability of raw materials to manufacture or test any such products; challenges related to our vaccine's formulation, two-dose schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or new variant-specific vaccines; the risk that we may not be able to recoup costs associated with our R&D and manufacturing efforts; risks associated with any changes in the way we approach or provide research funding for the BNT162 program or potential treatment for COVID-19; challenges and risks associated with the pace of our development programs; the risk that we may not be able to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine or any potential approved treatment, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine or potential treatment within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; pricing and access challenges for such products; challenges related to public vaccine confidence or awareness; trade restrictions; and competitive developments;

- trends toward managed care and healthcare cost containment, and our ability to obtain or maintain timely or adequate pricing or favorable formulary placement for our products;
- interest rate and foreign currency exchange rate fluctuations, including the impact of possible currency devaluations in countries experiencing high inflation rates;

- any significant issues involving our largest wholesale distributors or government customers, which account for a substantial portion of our revenues;
- the impact of the increased presence of counterfeit medicines in the pharmaceutical supply chain;

- any significant issues related to the outsourcing of certain operational and staff functions to third parties; and any significant issues related to our JVs and other third-party business arrangements;

- uncertainties related to general economic, political, business, industry, regulatory and market conditions including, without limitation, uncertainties related to the impact on us, our customers, suppliers and lenders and counterparties to our foreign-exchange and interest-rate agreements of challenging global economic conditions and recent and possible future changes in global financial markets;
- any changes in business, political and economic conditions due to actual or threatened terrorist activity, civil unrest or military action;

- the impact of product recalls, withdrawals and other unusual items, including uncertainties related to regulator-directed risk evaluations and assessments;
- trade buying patterns;
- the risk of an impairment charge related to our intangible assets, goodwill or equity-method investments;
- the impact of, and risks and uncertainties related to, restructurings and internal reorganizations, as well as any other corporate strategic initiatives, and cost-reduction and productivity initiatives, each of which requires upfront costs but may fail to yield anticipated benefits and may result in unexpected costs or organizational disruption;

Risks Related to Government Regulation and Legal Proceedings:

- the impact of any U.S. healthcare reform or legislation or any significant spending reductions or cost controls affecting Medicare, Medicaid or other publicly funded or subsidized health programs or changes in the tax treatment of employer-sponsored health insurance that may be implemented;
- U.S. federal or state legislation or regulatory action and/or policy efforts affecting, among other things, pharmaceutical product pricing, intellectual property, reimbursement or access or restrictions on U.S. direct-to-consumer advertising; limitations on interactions with healthcare professionals and other industry stakeholders; as well as pricing pressures for our products as a result of highly competitive insurance markets;
- legislation or regulatory action in markets outside of the U.S., including China, affecting pharmaceutical product pricing, intellectual property, reimbursement or access, including, in particular, continued government-mandated reductions in prices and access restrictions for certain biopharmaceutical products to control costs in those markets;
- the exposure of our operations globally to possible capital and exchange controls, economic conditions, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, as well as political unrest, unstable governments and legal systems and inter-governmental disputes;
- legal defense costs, insurance expenses, settlement costs and contingencies, including those related to actual or alleged environmental contamination;
- the risk and impact of an adverse decision or settlement and the adequacy of reserves related to legal proceedings;
- the risk and impact of tax related litigation;
- governmental laws and regulations affecting our operations, including, without limitation, changes in laws and regulations or their interpretation, including, among others, changes in tax laws and regulations, including, among others, any potential changes to the existing tax law by the current U.S. Presidential administration and Congress increasing the corporate tax rate and/or the tax rate on foreign earnings;

Risks Related to Intellectual Property, Technology and Security:

- any significant breakdown or interruption of our information technology systems and infrastructure;

- any business disruption, theft of confidential or proprietary information, extortion or integrity compromise resulting from a cyberattack;
- the risk that our currently pending or future patent applications may not be granted on a timely basis or at all, or any patent-term extensions that we seek may not be granted on a timely basis, if at all; and
- our ability to protect our patents and other intellectual property, including against claims of invalidity that could result in loss of exclusivity, unasserted intellectual property claims and in response to any pressure, or legal or regulatory action by, various stakeholders or governments that could potentially result in us not seeking intellectual property protection for or agreeing not to enforce or being restricted from enforcing intellectual property related to our products, including our vaccine to help prevent COVID-19 and potential treatments for COVID-19.

We cannot guarantee that any forward-looking statement will be realized. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in our subsequent reports on Form 10-Q, in each case including in the sections thereof captioned "Forward-Looking Information and Factors That May Affect Future Results" and "Item 1A. Risk Factors," and in our subsequent reports on Form 8-K.

This earnings release may include discussion of certain clinical studies relating to various in-line products and/or product candidates. These studies typically are part of a larger body of clinical data relating to such products or product candidates, and the discussion herein should be considered in the context of the larger body of data. In addition, clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate or a new indication for an in-line product, regulatory authorities may not share our views and may require additional data or may deny approval altogether.

The information contained on our website or any third-party website is not incorporated by reference into this earnings release.

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