Pfizer Logo

Pfizer Reports Second-Quarter 2023 Results

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- Second-Quarter 2023 Revenues of $12.7 Billion
  - Expected Decline in Paxlovid and Comirnaty(1) Revenues Drove 53% Operational Decrease in Second-Quarter 2023 Revenues
  - Second-Quarter 2023 Revenues from Comirnaty(1) and Paxlovid of $1.6 Billion
  - Excluding Contributions from Comirnaty(1) and Paxlovid, Revenues Grew 5% Operationally
- Second-Quarter 2023 Reported Diluted EPS(2) of $0.41, a Year-Over-Year Decline of 77%, and Adjusted Diluted EPS(3) of $0.67, a Year-Over-Year Decline of 67%
- Narrows 2023 Revenue Guidance(4) Range to $67 to $70 Billion and Adjusts 2023 Non-COVID Operational Revenue Growth Expectation to 6% to 8%
  - Maintains All Other Components of Full-Year 2023 Financial Guidance(4), Including Guidance for Adjusted Diluted EPS(3)
- Continues to Make Significant Progress on Executing an Unprecedented Number of Product and Indication Launches Expected to Contribute to Non-COVID Operational Revenue Growth in the Second Half of 2023

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) reported financial results for the second quarter of 2023. The company narrowed its 2023 revenue guidance(4) range to $67 to $70 billion, while maintaining its outlook for Adjusted diluted EPS(3) of $3.25 to $3.45.

The second-quarter 2023 earnings presentation and accompanying prepared remarks from management as well as the quarterly update to Pfizer's R&D pipeline can be found at www.pfizer.com.

EXECUTIVE COMMENTARY

Dr. Albert Bourla, Chairman and Chief Executive Officer, stated: "Pfizer has made significant progress toward our goal to launch 19 new products and indications in an 18-month span, having executed eleven launches thus far. We continue to build momentum in 2023, recently attaining key milestones for several products, including the U.S. launches of Prevnar 20 in pediatric patients and Zavzpret; U.S. approvals and launches for Abrysvo in older adults, Litfulo and the Talzenna plus Xtandi combination; U.S. approvals for Ngenla (expected to be available for prescribing this month) and Paxlovid; and U.S. regulatory filing acceptance for fidanacogene elaparvovec (Hemophilia B Gene Therapy).

Supporting our expectation to deliver robust operational growth in 2025 and beyond, we also reported data from several exciting pipeline candidates we believe have the potential to be significant future value-drivers, including Phase 3 data from marstacimab, Pfizer's novel, investigational anti-TFPI antibody being studied for the treatment of hemophilia A or B; further data from elranatamab, Pfizer's investigational BCMA CD3-targeted bispecific antibody currently being investigated in multiple myeloma; and first-in-human data from our pipeline of potential next-generation breast cancer treatments, including our novel CDK4, CDK2, and KAT6 inhibitors.

Finally, we continue to make progress toward our proposed acquisition of Seagen, a global biotechnology company that discovers, develops and commercializes transformative oncology medicines. In addition to receiving approval of the transaction from Seagen shareholders and planning for the potential integration of the two companies, we continue to work closely with regulators, including the Federal Trade Commission (FTC) and the European Commission (EC), and are working diligently to fulfill requests for further information from the FTC.

We look forward to continuing our progress in the second half of 2023, driven by commercial execution, scientific innovation and our never-ending commitment to delivering breakthroughs for patients."

David Denton, Chief Financial Officer and Executive Vice President, stated: "The second quarter of 2023 delivered solid 5% operational revenue growth, excluding our COVID-19 products, and our year-to-date results are in line with our expectations. Despite a few near-term individual product revenue challenges, we believe the company is well positioned for accelerated growth of our non-COVID products in the second half of 2023. The COVID environment continues to evolve rapidly and remains highly unpredictable. In spite of this uncertainty, the company is maintaining its focus on ensuring successful fall vaccinations during the respiratory infection season.

During the second quarter we successfully closed a $31 billion debt offering, the net proceeds of which we intend to use as part of the financing for Pfizer's proposed acquisition of Seagen. We continue to expect the transaction to close in late 2023 or early 2024, subject to the satisfaction of customary closing conditions. As we de-lever our capital structure after the close, we expect our strong balance sheet will continue to provide the flexibility for future dividend increases and share repurchases, as well as additional business development activity."

Results for the second quarter of 2023 and 2022[5] are summarized below.

OVERALL RESULTS

($ in millions, except per share amounts)	Second-Quarter			Six Months		
	2023	2022	Change	2023	2022	Change
Revenues	$ 12,734	$ 27,742	(54%)	$ 31,015	$ 53,402	(42%)
Reported Net Income[2]	2,327	9,906	(77%)	7,870	17,769	(56%)
Reported Diluted EPS[2]	0.41	1.73	(77%)	1.38	3.10	(56%)
Adjusted[3] Income	3,839	11,656	(67%)	10,876	20,993	(48%)
Adjusted[3] Diluted EPS	0.67	2.04	(67%)	1.90	3.66	(48%)

REVENUES

($ in millions)	Second-Quarter				Six Months			
			% Change				% Change	
	2023	2022	Total	Oper.	2023	2022	Total	Oper.

Global Biopharmaceuticals Business (Biopharma)[6]	**$ 12,418**	**$ 27,425**	**(55%)**	**(54%)**	**$ 30,389**	**$ 52,748**	**(42%)**	**(40%)**
Primary Care[6]	5,810	20,979	(72%)	(72%)	17,315	39,830	(57%)	(55%)
Specialty Care[6]	3,653	3,358	9%	12%	7,264	6,863	6%	10%
Oncology[6]	2,956	3,088	(4%)	(3%)	5,811	6,055	(4%)	(2%)
Business Innovation	**$ 316**	**$ 317**	**—**	**—**	**$ 626**	**$ 655**	**(4%)**	**(3%)**
TOTAL REVENUES	**$ 12,734**	**$ 27,742**	**(54%)**	**(53%)**	**$ 31,015**	**$ 53,402**	**(42%)**	**(40%)**

Beginning in the third quarter of 2022, Pfizer made several organizational changes to further transform its operations to better leverage its expertise in certain areas and in anticipation of potential future new product and indication launches. These changes included establishing a new commercial structure within Biopharma focused on three broad customer groups (primary care, specialty care and oncology)[6], optimizing Pfizer's end-to-end R&D operations and further prioritizing its internal R&D portfolio, as well as realigning certain enabling and platform functions across the organization to ensure alignment with this new operating structure.

In addition, in the first quarter of 2023, Pfizer established an operating segment, Business Innovation, that includes Pfizer CentreOne (PC1), the company's global contract development and manufacturing organization and a leading supplier of specialty active pharmaceutical ingredients; and Pfizer Ignite, a recently launched offering that provides strategic guidance and end-to-end R&D services to select innovative biotech companies that align with Pfizer's R&D focus areas.

Prior period amounts have been revised to conform to the current period presentation for all changes discussed above.

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].

CAPITAL ALLOCATION

During the first six months of 2023, Pfizer deployed its capital in a variety of ways, which primarily include the following two categories:

- Reinvesting capital into initiatives intended to enhance the future growth prospects of the company, including $5.2 billion invested in internal research and development projects, and
- Returning capital directly to shareholders through $4.6 billion of cash dividends, or $0.82 per share of common stock.

No share repurchases have been completed to date in 2023. As of August 1, 2023, Pfizer's remaining share repurchase authorization is $3.3 billion. Current financial guidance does not anticipate any share repurchases in 2023.

Second-quarter 2023 diluted weighted-average shares outstanding used to calculate Reported[2] and Adjusted[3] diluted EPS were 5,713 million shares.

2023 FINANCIAL GUIDANCE[4]

Pfizer narrowed its 2023 revenue guidance range to $67 to $70 billion, while maintaining its guidance for Adjusted diluted EPS[3]. The Company's updated guidance is presented below.

Revenues	$67.0 to $70.0 billion *(previously $67.0 to $71.0 billion)*
Adjusted[3] Cost of Sales as a Percentage of Revenues	28.0% to 30.0%
Adjusted[3] SI&A Expenses	$13.8 to $14.8 billion
Adjusted[3] R&D Expenses	$12.4 to $13.4 billion
Acquired IPR&D Expenses[4]	Approximately $0.1 billion
Adjusted[3] Other (Income)/Deductions	Approximately $1.5 billion of income
Effective Tax Rate on Adjusted[3] Income	Approximately 15.0%
Adjusted[3] Diluted EPS	$3.25 to $3.45

Changes in foreign exchange rates have had a minimal incremental impact since full-year 2023 guidance was issued. Please refer to Press Release Footnote (4) for additional information.

The midpoint of the guidance range for revenues reflects a 31% operational decrease compared to 2022 revenues. Company revenues are anticipated to be lower in 2023 than in 2022 due to expected revenue declines for Pfizer's COVID-19 products, partially offset by expected operational growth from our non-COVID-19 in-line portfolio, anticipated new product and indication launches and recently acquired products.

Excluding COVID-19 products, Pfizer is now expecting 6% to 8% operational revenue growth in 2023. This reduction of the Company's previously stated expectation of 7% to 9% non-COVID operational revenue growth reflects certain short-term headwinds, such as the U.S. approval for the Talzenna plus Xtandi combination for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC), versus an approval in the all-comers population; a shared clinical decision-making recommendation for Abrysvo from the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), versus a routine recommendation; and recent tornado damage to Pfizer's manufacturing facility in Rocky Mount, N.C. Over the longer term, the Company expects these short-term headwinds to be resolved, with its revenue outlook remaining intact versus its 2030 ambitions.

Revenue guidance for Pfizer's COVID-19 products is as follows:

- Comirnaty[1] revenues of approximately $13.5 billion, down 64% from 2022 results.
- Paxlovid revenues of approximately $8 billion, down 58% from 2022 results.
- In contrast to previous years, guidance for both products is no longer based primarily on expected deliveries under existing signed or committed supply contracts, but now also includes, among other things, an anticipated transition to traditional commercial markets in the U.S. in the second half of 2023.

The midpoint of the guidance range for Adjusted[3] diluted EPS reflects a 47% operational decrease compared to 2022, primarily driven by anticipated lower revenues from COVID-19 products, higher spending to support anticipated near-term launches and greater investment in certain late-stage pipeline projects.

Financial guidance for Adjusted[3] diluted EPS is calculated using approximately 5.72 billion weighted average shares outstanding, and assumes no share repurchases in 2023.

Pfizer's 2023 financial guidance is based on estimates and assumptions that are subject to significant uncertainties, particularly with regard to the anticipated performance of Comirnaty[1] and Paxlovid. See the *Overview of Our Performance, Operating Environment, Strategy and Outlook — Our 2022 Performance* and *— The Global Economic Environment* sections of Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) in Pfizer's 2022 Annual Report on Form 10-K; the *Overview of Our Performance, Operating Environment, Strategy and Outlook — Our First Quarter Financial Performance* and *— The Global Economic Environment* sections of MD&A in Pfizer's Quarterly Report on Form 10-Q for the quarterly period ended April 2, 2023; and Pfizer's fourth-quarter 2022 earnings press release (available at www.pfizer.com) for additional information.

QUARTERLY FINANCIAL HIGHLIGHTS (Second-Quarter 2023 vs. Second-Quarter 2022)

Second-quarter 2023 revenues totaled $12.7 billion, a decrease of $15.0 billion, or 54%, compared to the prior-year quarter, reflecting an operational decline of $14.7 billion, or 53%, primarily due to a decrease in Paxlovid and Comirnaty[1] revenues globally, as well as an unfavorable impact of foreign exchange of $283 million, or 1%. Excluding contributions from Comirnaty[1] and Paxlovid, company revenues grew $537 million, or 5%, operationally.

Second-quarter 2023 Paxlovid revenues declined $8.0 billion, or 98%, operationally compared with the prior-year quarter, primarily driven by no second quarter U.S. sales in anticipation of transition to traditional commercial markets in the second half of 2023, and lower contractual deliveries in most international markets.

Second-quarter 2023 Comirnaty[1] revenues declined $7.3 billion, or 82%, operationally compared with the prior-year quarter, largely driven by lower contracted deliveries and demand in international markets and lower U.S. government contracted deliveries, with anticipated transition to new variant vaccines globally and to traditional U.S. commercial market sales in the second half of 2023.

Excluding contributions from Comirnaty[1] and Paxlovid, second-quarter 2023 operational revenue growth was primarily driven by:

- Recently acquired products, Nurtec ODT/Vydura and Oxbryta, which contributed $247 million and $77 million in global revenues, respectively; and
- Vyndaqel family (Vyndaqel, Vyndamax, Vynmac) globally, up 43% operationally, largely driven by continued strong uptake of the transthyretin amyloid cardiomyopathy (ATTR-CM) indication, primarily in the U.S. and developed Europe;

partially offset primarily by lower revenues for:

- Inflectra in the U.S., down 81%, primarily driven by lower net price as a result of unfavorable changes in channel mix; and
- Ibrance, down 4% operationally, primarily driven by lower demand globally due to competitive pressure, lower clinical trial purchases internationally and planned price decreases in certain international developed markets.

GAAP Reported[2] Income Statement Highlights

SELECTED REPORTED COSTS AND EXPENSES[2]

($ in millions)	Second-Quarter				Six Months			
			% Change				% Change	
	2023	2022	Total	Oper.	2023	2022	Total	Oper.
Cost of Sales[2]	$ 3,237	$ 8,648	(63%)	(65%)	$ 8,122	$ 18,632	(56%)	(57%)
Percent of Revenues	25.4%	31.2%	N/A	N/A	26.2%	34.9%	N/A	N/A
SI&A Expenses[2]	3,497	3,048	15%	16%	6,914	5,642	23%	25%
R&D Expenses[2]	2,648	2,815	(6%)	(5%)	5,153	5,116	1%	2%
Acquired IPR&D Expenses[2]	33	1	*	*	55	356	(85%)	(85%)
Other (Income)/Deductions—net[2]	(347)	772	*	*	(277)	1,122	*	*
Effective Tax Rate on Reported Income[2]	(3.1%)	13.7%			7.5%	13.4%		

Second-quarter 2023 Cost of Sales[2] as a percentage of revenues decreased by 5.8 percentage points compared with the prior-year quarter, primarily driven by favorable changes in sales mix, including lower sales of Comirnaty[1] and, to a much lesser extent, by lower write-offs for Comirnaty[1] inventory that exceeded or was expected to exceed its approved shelf life prior to being used; partially offset by lower sales of Paxlovid.

Second-quarter 2023 SI&A Expenses[2] increased 16% operationally compared with the prior-year quarter, primarily reflecting increased investments to support recently acquired and launched products and the expected Paxlovid commercial launch, as well as an increase in deferred compensation savings plan expenses, partially offset by a lower provision for U.S. healthcare reform fees associated with lower sales of Paxlovid and Comirnaty[1].

Second-quarter 2023 R&D Expenses[2] decreased 5% operationally compared with the prior-year quarter, primarily driven by lower spending on programs to prevent and treat COVID-19 and a decrease in the value of the portfolio performance share grants reflecting the decrease in the price of Pfizer's common stock in the second quarter of 2023; partially offset by increased investments to develop recently acquired assets and certain vaccine programs, as well as activities to support upcoming product launches.

Pfizer recorded $347 million of other income—net[2] in the second quarter of 2023 compared with $772 million of other deductions—net[2] in the second quarter of 2022. The period-over-period change was primarily driven by:

- net gains on equity securities in the second of quarter 2023 versus net losses on equity securities recognized in the prior-year quarter; and
- net periodic benefit credits associated with pension and postretirement plans incurred in the second quarter of 2023 versus net periodic benefit costs recognized in the second quarter of 2022.

Pfizer's effective tax rate on Reported income[2] for the second quarter of 2023 is negative primarily due to tax benefits in the second quarter of 2023 related to global income tax resolutions in multiple tax jurisdictions spanning multiple tax years and a favorable change in the jurisdictional mix of earnings.

Adjusted[3] Income Statement Highlights

SELECTED ADJUSTED[3] COSTS AND EXPENSES

($ in millions)	Second-Quarter				Six Months			
			% Change				% Change	
	2023	2022	Total	Oper.	2023	2022	Total	Oper.
Adjusted[3] Cost of Sales	$ 3,072	$ 8,625	(64%)	(66%)	$ 7,818	$ 18,582	(58%)	(58%)
Percent of Revenues	24.1%	31.1%	N/A	N/A	25.2%	34.8%	N/A	N/A
Adjusted[3] SI&A Expenses	3,419	2,900	18%	20%	6,769	5,396	25%	28%
Adjusted[3] R&D Expenses	2,627	2,811	(7%)	(6%)	5,118	5,106	—	1%
Adjusted[3] Other (Income)/Deductions—net	(551)	(377)	46%	25%	(1,079)	(783)	38%	24%
Effective Tax Rate on Adjusted[3] Income	6.8%	15.4%			11.6%	15.1%		

Reconciliations of certain Reported[2] to non-GAAP 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 May 2, 2023)

Product Developments

- **Abrysvo (Respiratory Syncytial Virus Vaccine) – Older Adults**
  - In May 2023, Pfizer announced the U.S. Food and Drug Administration (FDA) approved Abrysvo, the company's bivalent respiratory syncytial virus (RSV) prefusion F (RSVpreF) vaccine, for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years and older. The CDC's ACIP subsequently recommended Abrysvo for use in adults 60 years of age and older, using shared clinical decision making. This recommendation was published in the CDC's *Morbidity and Mortality Weekly Report (MMWR)* in July 2023, triggering the initiation of Medicare and Commercial coverage.
  - In July 2023, Pfizer announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion, recommending the granting of a marketing authorization for RSVpreF for older adults. The CHMP's positive opinion will now be reviewed by the EC. The EC will take the CHMP's recommendation under advisement to decide whether to approve RSVpreF, whose trade name in the European Union (EU) will be Abrysvo. The EC's final decision is expected in the coming weeks.
  - In June 2023, Pfizer presented for the first time an analysis of initial vaccine efficacy data for mid-RSV season two in the Northern Hemisphere from the ongoing pivotal Phase 3 trial in older adults, as well as presented positive top-line results from a Phase 3 study that support the coadministration of Abrysvo with flu vaccine in older adults at the CDC's ACIP June meeting.
- **Abrysvo (Respiratory Syncytial Virus Vaccine) – Maternal Immunization for Infants**
  - In July 2023, Pfizer announced that the CHMP of the EMA adopted a positive opinion, recommending the granting of a marketing authorization for RSVpreF for maternal immunization to help protect infants. The CHMP's positive opinion will now be reviewed by the EC. The EC will take the CHMP's recommendation under advisement to decide whether to approve RSVpreF, whose trade name in the EU will be Abrysvo. The EC's final decision is expected in the coming weeks.

- In May 2023, Pfizer announced that the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted that available data are adequate to support the efficacy and safety of its RSVpreF vaccine candidate for pregnant individuals to help prevent RSV disease in infants. The vaccine is currently under FDA review for the prevention of medically attended lower respiratory tract disease (MA-LRTD) and severe MA-LRTD caused by RSV in infants from birth up to six months of age by active immunization of pregnant individuals. The role of the VRBPAC is to provide recommendations to the FDA; however, these recommendations are not binding. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is in August 2023, followed by discussion at a meeting of the ACIP.

- **Braftovi (encorafenib) and Mektovi (binimetinib)** – In June 2023, Pfizer announced the first detailed results from the Phase 2 PHAROS study, which is evaluating the efficacy and safety of Braftovi given in combination with Mektovi to patients with *BRAF* V600E-mutant metastatic non-small cell lung cancer (NSCLC). The results were presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in the *Journal of Clinical Oncology*. The FDA is reviewing the company's Supplemental New Drug Applications (sNDAs) for Braftovi + Mektovi for patients with metastatic NSCLC with a *BRAF* V600E mutation based on the results from the PHAROS trial with a PDUFA goal date for a decision by the FDA in fourth quarter 2023.
- **Comirnaty (COVID-19 vaccine, mRNA)[(8)]**
  - In June 2023, Pfizer and BioNTech SE (BioNTech) announced the companies have submitted regulatory applications to the FDA and EMA for their Omicron XBB.1.5-adapted monovalent COVID-19 vaccine for the 2023-2024 fall and winter season. These filings follow guidance from the FDA's VRBPAC, EMA and other health authorities that updated vaccines targeting Omicron XBB.1 sublineages may help to protect against COVID-19 during the upcoming fall and winter season. The companies expect to be ready to ship the adapted vaccines immediately upon regulatory authorization/approval.
  - In May 2023, Pfizer and BioNTech announced they have reached an agreement with the EC to amend their existing contract to deliver COVID-19 vaccines to the EU. The amended agreement includes rephasing of delivery of doses annually through 2026 and an aggregate volume reduction, providing additional flexibility for EU Member States. The EC will maintain access to future adapted COVID-19 vaccines and the ability to donate doses, in alignment with the original agreement.
- **Litfulo (ritlecitinib)**
  - In July 2023, Pfizer announced that the CHMP of the EMA adopted a positive opinion for Litfulo—a kinase inhibitor that inhibits Janus kinase 3 (JAK3) and the tyrosine kinase expressed in hepatocellular carcinoma (TEC) family of kinases—recommending marketing authorization of once-daily 50 mg for individuals 12 years of age and older with severe alopecia areata. The EC will review the CHMP recommendation and is expected to make a final decision in the coming months.
  - In June 2023, Pfizer announced the FDA approved Litfulo, a once-daily oral treatment, for individuals 12 years of age and older with severe alopecia areata. Litfulo is the first and only treatment approved by the FDA for adolescents (12+) with severe alopecia areata.
- **Ngenla (somatrogon-ghla)** – In June 2023, Pfizer and OPKO Health Inc. announced the FDA approved Ngenla, a once-weekly, human growth hormone analog for the treatment of pediatric patients aged three years and older who have growth failure due to inadequate secretion of endogenous growth hormone. Ngenla is approved for the treatment of pediatric growth hormone deficiency in more than 40 markets including Canada, Australia, Japan, and EU Member States.
- **Paxlovid (nirmatrelvir tablets and ritonavir tablets)** [(8)] – In May 2023, Pfizer announced the FDA approved Paxlovid for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid has been available in the U.S. since December 2021 under Emergency Use Authorization (EUA), and the overall benefit/risk profile

and indication for use in eligible adults remain consistent with the EUA. At this time, the U.S. government will continue to oversee the distribution of Paxlovid, but Pfizer expects a transition to traditional commercial markets in the second half of the year.

- **Prevnar 20 (20-valent pneumococcal conjugate vaccine)** – In June 2023, Pfizer announced the CDC's ACIP unanimously voted to recommend Prevnar 20 for routine vaccination for all children under two years of age, for eligible children aged 2-18 years with certain underlying medical conditions, and a catch-up dose for children with an incomplete pneumococcal conjugate vaccine vaccination status.
- **Talzenna (talazoparib)** – In June 2023, Pfizer announced the FDA approved Talzenna, an oral poly ADP-ribose polymerase (PARP) inhibitor, in combination with Xtandi (enzalutamide), for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC). The approval was based on the statistically significant and clinically meaningful radiographic progression-free survival (rPFS) data from the Phase 3 TALAPRO-2 trial. A Marketing Authorization Application (MAA) for the Talzenna and Xtandi combination has been accepted for review by the EMA, and Pfizer has shared data with additional regulatory agencies to support regulatory filings.

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.

- **Aztreonam-avibactam (PF-06947387)** – In June 2023, Pfizer announced positive results from the Phase 3 program comprising the REVISIT (NCT03329092) and ASSEMBLE (NCT03580044) studies evaluating the efficacy, safety and tolerability of the novel investigational antibiotic combination aztreonam-avibactam (ATM-AVI) in treating serious bacterial infections due to Gram-negative bacteria, including metallo-?-lactamase (MBL)-producing multidrug-resistant pathogens for which there are limited or no treatment options. Data support that ATM-AVI is effective and well-tolerated, with no new safety findings and a similar safety profile to aztreonam alone. Data from the REVISIT and ASSEMBLE studies are expected to form the basis for planned regulatory filings in the EU, United Kingdom, China and the U.S. in the second half of 2023. Pfizer holds the global rights to commercialize ATM-AVI outside of the U.S. and Canada, where the rights are held by its development partner, AbbVie.
- **Danuglipron (PF-06882961)** – In June 2023, Pfizer announced its decision to continue to advance its oral glucagon-like peptide-1 receptor agonist (GLP-1RA) candidate danuglipron toward late-stage development for the potential treatment of adults with obesity and Type 2 diabetes mellitus, subject to results from the ongoing Phase 2 trial; and to discontinue the clinical development of a second GLP-1RA candidate lotiglipron (PF-07081532). The company expects to finalize plans for the danuglipron late-stage program by the end of 2023 and also is developing a once-daily modified release version.
- **Elranatamab (PF-06863135)** – In June 2023, Pfizer announced updated data from the MagnetisMM clinical development program for elranatamab, an investigational B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody (BsAb) currently being investigated in multiple myeloma (MM). Data across 13 abstracts were shared at the 2023 ASCO Annual Meeting, including new data from the Phase 2 MagnetisMM-3 clinical trial in patients with relapsed or refractory multiple myeloma (RRMM) who were previously treated with BCMA-directed therapy, supporting the safety and efficacy of elranatamab regardless of prior BCMA-directed treatment history. Additional presentations included new 15-month data from BCMA-naïve patients, subgroup analyses among difficult-to-treat patient populations, real-world treatment patterns for triple-class refractory MM and indirect comparisons/comparative effectiveness between elranatamab and other therapies. Elranatamab is currently under review by

regulatory agencies, including the FDA, which has granted priority review for the company's Biologics License Application (BLA) in RRMM with a PDUFA date in August 2023.

- **Fidanacogene elaparvovec (Hemophilia B Gene Therapy)** – In June 2023, Pfizer announced the FDA accepted for review the company's BLA for fidanacogene elaparvovec for the treatment of adults with hemophilia B and that the European MAA for fidanacogene elaparvovec also has been accepted and is under review by the EMA. Fidanacogene elaparvovec is a novel investigational gene therapy that contains a bio-engineered adeno-associated virus capsid and a high-activity variant of human coagulation Factor IX gene. The FDA has set a PDUFA goal date in the second quarter of 2024.
- **GBS6 (PF-06760805, Group B Streptococcus Vaccine)** – In July 2023, Pfizer announced data from a Phase 2 study investigating its hexavalent capsular polysaccharide (CPS) conjugate Group B Streptococcus (GBS) vaccine candidate, GBS6, being developed for maternal administration to protect infants against invasive GBS disease. In stage two of the three-part study, which enrolled 360 healthy pregnant individuals, GBS6 generated robust maternal antibody responses against the six GBS CPS serotypes included in the vaccine, and these antibodies were efficiently transferred to infants at ratios of ~0.4-1.3 depending on GBS6 group. Based on a parallel natural history study conducted in South Africa, the Phase 2 study immunogenicity data suggest that GBS6 may offer meaningful protection against invasive GBS disease in newborns and young infants. The results were published in *The New England Journal of Medicine* and will inform a planned Phase 3 clinical development program. GBS6 was granted PRIME designation by the EMA's CHMP and has received Breakthrough Therapy Designation from the U.S. FDA.
- **Marstacimab (PF-06741086)** – In May 2023, Pfizer announced that the pivotal Phase 3 BASIS clinical trial (NCT03938792) evaluating marstacimab met its primary endpoints, having demonstrated statistically significant and clinically meaningful effects. Marstacimab is a novel, investigational anti-tissue factor pathway inhibitor (anti-TFPI) being studied for the treatment of hemophilia A or B for people with and without inhibitors to Factor VIII or Factor IX. The BASIS trial demonstrated that prophylactic treatment with marstacimab resulted in a statistically significant and clinically relevant effect on annualized bleeding rate in people living with severe hemophilia A and moderately severe to severe hemophilia B without inhibitors. Analyses of the full Phase 3 dataset are ongoing, and results will be presented at an upcoming scientific conference. Pfizer will discuss these data with regulatory authorities, with the goal of initiating regulatory filings in the coming months. The inhibitor cohort of the BASIS trial is completing enrollment and is expected to read out as early as late 2024.

Corporate Developments

- In July 2023, Pfizer announced changes to its executive leadership team to further advance its aspirations to discover and develop new medicines and vaccines, with an emphasis on oncology. Chris Boshoff, M.D., Ph.D., has joined Pfizer's Executive Leadership Team as Chief Oncology Research and Development Officer and Executive Vice President reporting to Chairman and Chief Executive Officer, Albert Bourla. Under his leadership, Pfizer will continue to invest in its fight against cancer, and Dr. Boshoff will be the single point of accountability for the entire oncology pipeline—from discovery to early- and late-phase clinical development. Mikael Dolsten, M.D., Ph.D., Chief Scientific Officer, President, Pfizer Research & Development, has expanded his role to lead all discovery, early- and late-stage clinical development for all non-oncology therapeutic areas, including Vaccines, Inflammation and Immunology, Internal Medicine and Infectious Diseases as well as non-malignant hematology and rare neuromuscular diseases. As a result of these moves, William Pao, M.D., Ph.D., Chief Development Officer and Executive Vice President, will be leaving Pfizer to pursue new opportunities outside the company.
- In July 2023, Pfizer and Flagship Pioneering, Inc. (Flagship) announced the companies have partnered to create a new pipeline of innovative medicines. Under the terms of the novel agreement, Flagship and Pfizer will each invest $50 million upfront to explore opportunities to develop 10 single-asset programs by

leveraging Flagship's ecosystem of more than 40 human health companies and multiple biotechnology platforms. Pfizer will fund and have an option to acquire each selected development program. Flagship and its bioplatform companies will be eligible to receive up to $700 million in milestones and royalties for each successfully commercialized program.

- In May 2023, Pfizer completed a $31 billion debt offering consisting of eight tranches of notes (collectively, the "Notes"). The Notes were issued by Pfizer's wholly-owned subsidiary, Pfizer Investment Enterprises Pte. Ltd., and are fully and unconditionally guaranteed on a senior unsecured basis by Pfizer. Pfizer intends to use the net proceeds of the offering as part of the financing for Pfizer's proposed acquisition of Seagen Inc.
- In May 2023, Pfizer and Thermo Fisher Scientific Inc. announced they have entered into a collaboration agreement to help increase local access for next-generation sequencing (NGS)-based testing for lung and breast cancer patients in more than 30 countries across Latin America, Africa, the Middle East and Asia where advanced genomic testing has previously been limited or unavailable. Under the agreement, Pfizer will explore ways to enable affordable patient access for NGS testing in these cancers and work to raise healthcare provider awareness regarding the benefits of advanced testing.

Additional Developments

- In July 2023, Pfizer announced the company's immediate efforts to provide relief and repair the damage caused to its manufacturing facility in Rocky Mount, N.C., after a tornado swept through the town. The facility is a key producer of sterile injectables and is responsible for manufacturing nearly 25 percent of all Pfizer's sterile injectables—including anesthesia, analgesia, therapeutics, anti-infectives and neuromuscular blockers—which is nearly eight percent of all the sterile injectables used in U.S. hospitals. Most of the damage was caused to the warehouse facility, which stores raw materials, packaging supplies and finished medicines. The company is working diligently to move product to other nearby sites for storage and to identify sources to replace damaged raw materials and supplies. It also is exploring alternative manufacturing locations for production across its significant manufacturing presence in the U.S. and internationally and across its partner network. After an initial assessment, there does not appear to be major damage to the production areas, and Pfizer is committed to rapidly restoring full function to the site. Pfizer and the Pfizer Foundation also are providing financial support to help local communities affected by the natural disaster.
- In June 2023, Pfizer announced it entered into a manufacturing capacity reservation agreement with the European Health and Digital Executive Agency of the EC, which provides the EU access to doses of an mRNA-based vaccine should one be developed to protect against a future pandemic-causing disease. The company will continue to pursue similar agreements with other countries and multi-lateral organizations, building on the reliability and partnerships forged during the COVID-19 pandemic response.

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/Q2-2023-PFE-Earnings-Release

(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 financial schedules and product revenue tables attached to the press release located at the hyperlink above, and the attached disclosure notice.

(1) As used in this document, "Comirnaty" refers to, as applicable, and as authorized or approved, the Pfizer-BioNTech COVID-19 Vaccine, the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), the Comirnaty Original/Omicron BA.1 Vaccine, and Comirnaty Original/Omicron BA.4/BA.5

Vaccine. In the U.S., the original monovalent mRNA COVID-19 vaccine is no longer emergency use authorized or CDC-recommended, although Comirnaty remains a licensed vaccine. “Comirnaty” includes direct sales and alliance revenues related to sales of the above-mentioned vaccines, which are recorded within Pfizer’s Primary Care customer group. It does not include revenues for certain Comirnaty-related manufacturing activities performed on behalf of BioNTech, which are included in the Pfizer CentreOne contract development and manufacturing organization. Revenues related to these manufacturing activities totaled $6 million and $10 million for the second quarter and the first six months of 2023, respectively, and $55 million and $101 million for the second quarter and the first six months of 2022, 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. common shareholders 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 Adjusted diluted EPS are defined as U.S. GAAP net income attributable to Pfizer Inc. common shareholders and Reported diluted EPS attributable to Pfizer Inc. common shareholders before the impact of amortization of intangible assets, certain acquisition-related items, discontinued operations and certain significant items. See the accompanying reconciliations of certain GAAP Reported to Non-GAAP Adjusted information for the second quarter and the first six months of 2023 and 2022. 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)]. See the *Non-GAAP Financial Measure: Adjusted Income* section of Management’s Discussion and Analysis of Financial Condition and Results of Operations in Pfizer’s 2022 Annual Report on Form 10-K and the accompanying *Non-GAAP Financial Measure: Adjusted Income* section of the press release located at the hyperlink above for a definition of each component of Adjusted income as well as other relevant information.

(4) Pfizer does not provide guidance for GAAP Reported financial measures (other than revenues and acquired in-process R&D (IPR&D) expenses) 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 unusual gains and losses, certain acquisition-related expenses, gains and losses from equity securities, actuarial gains and losses from pension and postretirement plan remeasurements, potential future asset impairments and pending litigation 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 2023 reflects the following:

- Does not assume the completion of any business development transactions not completed as of July 2, 2023, except for signed transactions, if any, through mid-July 2023, which are expected to give rise to acquired IPR&D expenses during fiscal 2023.
- Reflects an anticipated negative revenue impact of approximately $0.2 billion due to recent and expected generic and biosimilar competition for certain products that have recently lost patent protection or that are anticipated to lose patent protection during fiscal-year 2023.
- Reflects expected impacts from certain short-term headwinds, such as the U.S. approval for the Talzenna plus Xtandi combination for the treatment of adult patients with HRR gene-mutated mCRPC, versus an approval in the all-comers population; a shared-clinical decision-making recommendation for Abrysvo from the CDC’s ACIP, versus a routine recommendation; and recent tornado damage to Pfizer’s facility in Rocky Mount, N.C.

- Exchange rates assumed are a blend of actual rates in effect through the second quarter of 2023 and end of June 2023 rates for the remainder of the year. Financial guidance reflects the anticipated unfavorable impact of approximately $0.7 billion on revenues and approximately $0.16 on Adjusted[(3)] diluted EPS as a result of changes in foreign exchange rates relative to the U.S. dollar compared to foreign exchange rates from 2022.
- Guidance for Adjusted[(3)] diluted EPS assumes diluted weighted-average shares outstanding of approximately 5.72 billion shares, and assumes no share repurchases in 2023.

(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 second quarter and first six months for U.S. subsidiaries reflects the three and six months ended on July 2, 2023 and July 3, 2022, while Pfizer's second quarter and first six months for subsidiaries operating outside the U.S. reflects the three and six months ended on May 28, 2023 and May 29, 2022.

(6) Beginning in the third quarter of 2022, Pfizer made several organizational changes to further transform its operations to better leverage its expertise in certain areas and in anticipation of potential future new product and indication launches. Biopharma, Pfizer's innovative science-based biopharmaceutical business, is operating under a new commercial structure designed to better support and optimize performance across three broad customer groups:

- Primary Care, consisting of the former Internal Medicine and Vaccines product portfolios, products for COVID-19 prevention and treatment, and potential future mRNA and antiviral products.
- Specialty Care, consisting of the former Inflammation & Immunology, Rare Disease and Hospital (excluding Paxlovid) product portfolios.
- Oncology, consisting of the former Oncology product portfolio.

(7) References to operational variances in this press release pertain to period-over-period changes 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 because 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) The Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) and certain uses of Paxlovid have not been approved or licensed by the FDA. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent has been authorized by the FDA under an EUA to prevent COVID-19 in individuals aged 6 months and older. Paxlovid has been authorized for emergency use by the FDA under an EUA for the treatment of mild-to-moderate COVID-19 in pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death. 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 during the COVID-19 pandemic under Section 564(b)(1) of the FFDCA unless the declaration is terminated or authorization revoked sooner. Please see the EUA Fact Sheets at www.covid19oralrx.com and www.cvdvaccine-us.com.

DISCLOSURE NOTICE: Except where otherwise noted, the information contained in this earnings release and the related attachments is as of August 1, 2023. 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, strategy and prospects; our

Environmental, Social and Governance (ESG) priorities, strategy and goals; expectations for our product pipeline, in-line products and product candidates, including anticipated regulatory submissions, data read-outs, study starts, approvals, launches, clinical trial results and other developing data, revenue contribution and projections, potential pricing and reimbursement, potential market dynamics and size, 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, including our proposed acquisition of Seagen, and our ability to successfully capitalize on these opportunities; manufacturing and product supply; our ongoing efforts to respond to COVID-19, including Comirnaty (as defined in this earnings release) and our oral COVID-19 treatment (Paxlovid); 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,” “potential,” “hope” 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 research and development (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; risks associated with preliminary, early stage or interim 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, including the scope of indicated patient populations, product dosage, manufacturing processes, safety and/or other matters, including decisions relating to emerging developments regarding potential product impurities; the impact of, or uncertainties regarding the ability to obtain, 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 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;

- risks and uncertainties related to Pfizer's proposed acquisition of Seagen, including, among other things, risks related to the satisfaction or waiver of the conditions to closing the proposed acquisition (including the failure to obtain necessary regulatory approvals) in the anticipated timeframe or at all, including the possibility that the proposed acquisition does not close; risks related to the ability to realize the anticipated benefits of the proposed acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the transaction making it more difficult to maintain business and operational relationships; negative effects of the announcement or the consummation of the proposed acquisition on the market price of Pfizer's common stock and/or operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition or Seagen's business; risks related to the financing of the transaction; other business effects and uncertainties, including the effects of industry, market, business, economic, political or regulatory conditions; future exchange and interest rates; changes in tax and other laws, regulations, rates and policies; the impact of the proposed acquisition on future business combinations or disposals; uncertainties regarding the commercial success of Pfizer's and Seagen's commercialized and pipeline products; the uncertainties inherent in R&D; whether and when drug applications may be filed in any jurisdictions for Pfizer's or Seagen's pipeline products; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such products will be commercially successful; and competitive developments;
- competition, including from new product entrants, in-line branded products, generic products, private label products, biosimilars and product candidates that treat or prevent diseases and conditions similar to those treated or intended to be prevented 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 facilities or third-party facilities that we rely on; and legal or regulatory actions;
- the impact of public health outbreaks, epidemics or pandemics (such as COVID-19) on our business, operations and financial condition and results, including impacts on our employees, manufacturing, supply chain, sales and marketing, R&D and clinical trials;
- risks and uncertainties related to our efforts to develop and commercialize our COVID-19 products, as well as challenges related to their manufacturing, supply and distribution, including, among others, the risk that demand for any of our COVID-19 products may be reduced, no longer exist or not meet expectations, which may lead to excess inventory on-hand and/or in the channel, inventory write-offs or reduced revenues; challenges related to and uncertainties regarding the timing of a transition to the commercial market for any of our products; uncertainties related to the public's adherence to vaccines, boosters and treatments; risks related to our ability to achieve our revenue forecasts for Comirnaty and Paxlovid or any potential future COVID-19 vaccines or treatments; uncertainties inherent in R&D, 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 Phase 1/2/3 or Phase 4 data for Comirnaty or any vaccine candidate in the BNT162 program or Paxlovid or any future COVID-19 treatment) in any of our studies in pediatrics, adolescents or adults or real world evidence, including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data or further information regarding the quality of pre-clinical, clinical or safety data, including by audit or inspection; the ability to produce comparable clinical or other results for Comirnaty, any vaccine candidate or other vaccines that may result from the BNT162 program, Paxlovid or any future COVID-19 treatment or any

other COVID-19 program, including the rate of effectiveness and/or efficacy, safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial for any such products and additional studies, in real-world data studies or in larger, more diverse populations following commercialization; the ability of Comirnaty, any vaccine candidate or any future vaccine to prevent, or Paxlovid or any future COVID-19 treatment to be effective against, COVID-19 caused by emerging virus variants; the risk that use of Comirnaty or Paxlovid 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, Paxlovid or other COVID-19 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 existing or future pre-clinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for Comirnaty or any future vaccines in additional populations, for a potential booster dose for Comirnaty, any vaccine candidate or any potential future vaccines (including potential future annual boosters or re-vaccinations), 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, or existing EUAs, will expire or terminate; whether and when submissions to request emergency use or conditional marketing authorizations for Paxlovid or any future COVID-19 treatment and/or any drug applications and/or EUA applications or amendments to any such applications for any indication for Paxlovid or any future COVID-19 treatment may be filed in particular jurisdictions, and if obtained, whether or when such EUA or licenses, or existing EUAs, will expire or terminate; whether and when any application that may be pending or filed for Comirnaty, any vaccine candidate or other vaccines that may result from the BNT162 program, Paxlovid or any future COVID-19 treatment or any other COVID-19 program 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 the authorization or approval of products or therapies developed 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; risks related to the availability of raw materials to manufacture or test any such products; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; challenges and risks related to medication errors such as prescribing or dispensing the wrong strength, improper dosing and self-administration errors; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines, potential combination respiratory vaccines or next generation COVID-19 treatments; 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, Paxlovid or any other COVID-19 program; challenges and risks associated with the pace of our development programs; the risk that we may not be able to maintain manufacturing capacity or access to logistics or supply channels commensurate with global demand for our COVID-19 products, which would negatively impact our ability to supply our COVID-19 products within the projected time periods; whether and when additional supply or purchase agreements will be reached or existing agreements will be completed or renegotiated; uncertainties regarding the ability to obtain recommendations from vaccine or treatment 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 confidence in, or awareness of Comirnaty or Paxlovid, including challenges driven by misinformation or disinformation, access, concerns about clinical data integrity, or prescriber and pharmacy education; uncertainties around future changes to applicable healthcare policies and guidelines issued by the U.S. federal government in connection with the declared termination of the federal government's COVID-19 public health emergency as of May 11, 2023; trade restrictions; potential third-party royalties or other claims related to Comirnaty or Paxlovid; 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 and monetary policy actions 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 or vaccines 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, such as inflation, and recent and possible future changes in global financial 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, the impact of political or civil unrest or military action, including the ongoing conflict between Russia and Ukraine and its economic consequences, unstable governments and legal systems, inter-governmental disputes, disruptions related to climate change and natural disasters, including uncertainties related to the impact of the recent tornado at our manufacturing facility in Rocky Mount, North Carolina;
- any changes in business, political and economic conditions due to actual or threatened terrorist activity, geopolitical instability, 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, including our ongoing evaluation of our product portfolio for the potential presence or formation of nitrosamines;
- 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 growth strategies, 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;
- the ability to successfully achieve our climate goals and progress our environmental sustainability and other ESG priorities;

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, including the Inflation Reduction Act of 2022, 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., such as China or Europe, including, without limitation, laws related to pharmaceutical product pricing, intellectual property, medicine safety, environmental impact of medicines, 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;
- 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 risk related to adequacy of reserves related to legal proceedings;
- the risk and impact of tax related litigation and investigations;
- governmental laws and regulations affecting our operations, including, without limitation, the Inflation Reduction Act of 2022, changes in laws and regulations or their interpretation, including, among others, changes in tax laws and regulations internationally and in the U.S., the adoption of global minimum taxation requirements outside the U.S. and potential changes to existing tax law by the current U.S. Presidential administration and Congress;

Risks Related to Intellectual Property, Technology and Security:

- any significant breakdown or interruption of our information technology systems and infrastructure (including cloud services);
- any business disruption, theft of confidential or proprietary information, security threats on facilities or infrastructure, extortion or integrity compromise resulting from a cyber-attack or other malfeasance by, but not limited to, nation states, employees, business partners or others;
- 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
- risks to our products, patents and other intellectual property, such as: (i) claims of invalidity that could result in loss of exclusivity; (ii) claims of patent infringement, including asserted and/or unasserted intellectual property claims; (iii) claims we may assert against intellectual property rights held by third parties; (iv) challenges faced by our collaboration or licensing partners to the validity of their patent rights; or (v) any pressure, or legal or regulatory action by, various stakeholders or governments that could potentially result in us not seeking intellectual property protection or agreeing not to enforce or being restricted from enforcing intellectual property rights related to our products, including Comirnaty and Paxlovid.

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, 2022 and in our subsequent report 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. All trademarks mentioned are the property of their owners.

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