

Pfizer Reports Full-Year 2023 Results and Reaffirms Full-Year 2024 Financial Guidance

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- 2023 Sets Stage for Future Growth Potential: Completed Seagen Acquisition, Creating World-Class Oncology Organization; Launched Significant Number of New Products and Indications; and Realigned Commercial Organization to Improve Focus, Speed and Execution
- Full-Year 2023 Revenues of \$58.5 Billion
 - Expected Decline in Comirnaty⁽¹⁾ and Paxlovid Revenues Drove 41% Operational Decrease in Year-Over-Year Revenues
 - Excluding Contributions from Comirnaty⁽¹⁾ and Paxlovid, Revenues Grew 7% Operationally, Driven by a Combination of New Product and Indication Launches and In-Line Product Growth
- Full-Year 2023 Reported⁽²⁾ Diluted EPS of \$0.37, Down 93% Year-Over-Year, and Adjusted⁽³⁾ Diluted EPS of \$1.84, Down 72% Year-Over-Year, Significantly Impacted by One-Time Events⁽⁴⁾
- Fourth-Quarter 2023 Revenues of \$14.2 Billion
 - Expected Decline in Comirnaty⁽¹⁾ and Paxlovid Revenues Drove 42% Operational Decrease in Fourth-Quarter Revenues
 - Excluding Contributions from Comirnaty⁽¹⁾ and Paxlovid, Revenues Grew 8% Operationally
- Fourth-Quarter 2023 Reported⁽²⁾ Diluted Loss Per Share (LPS) of \$(0.60) and Adjusted⁽³⁾ Diluted EPS of \$0.10, Significantly Impacted by One-Time Events⁽⁴⁾
- On Track to Deliver at Least \$4 Billion in Annual Net Cost Savings by End of 2024 from Previously Announced Cost Realignment Program
- Reaffirms Full-Year 2024 Guidance⁽⁵⁾ Provided on December 13, 2023, of Revenues of \$58.5 to \$61.5 Billion and Adjusted⁽³⁾ Diluted EPS of \$2.05 to \$2.25

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) reported financial results for fourth quarter and full-year 2023 and reaffirmed its 2024 financial guidance⁽⁵⁾ provided on December 13, 2023.

The fourth-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: "We are encouraged by the strong performance of our non-COVID products in the fourth quarter of 2023, including significant contributions from new launches and robust year-over-year growth for several key in-line brands. In 2023, Pfizer received a record number of nine new molecular entity approvals by the U.S. Food and Drug Administration (FDA)—medicines and vaccines that are expected to favorably impact Pfizer's performance in the coming years.

"In addition, we completed the acquisition of Seagen in December 2023, a critical step toward our goal to achieve world-class Oncology leadership. With the combined strength of Pfizer's and Seagen's talent, portfolios

and platforms, we believe we have the potential to transform outcomes by delivering cancer medicines that help patients live better and longer lives. We look forward to sharing the vision of the new Pfizer Oncology Division at our announced Oncology Innovation Day on Thursday, February 29.

“We are entering 2024 with a solid foundation. We believe our commitment to execution, maximizing the performance of our new products, and delivering the next wave of pipeline innovation will fuel Pfizer’s growth and make a difference in the lives of patients everywhere.”

David Denton, Chief Financial Officer and Executive Vice President, stated: “We are pleased with the strong 8% operational revenue growth of Pfizer’s non-COVID products in the fourth quarter of 2023, achieving our full-year 2023 non-COVID operational revenue growth target of 6% to 8%. In addition, we are on track to deliver at least \$4.0 billion in annual net cost savings by the end of 2024 from our cost realignment program. We are prepared to execute our commercial strategy to drive continued growth from our newly launched and acquired products, and to deliver on our targeted cost savings that we expect will expand our operating margins in 2024 and beyond.”

Results for fourth-quarter and full-year 2023 and 2022⁽⁶⁾ are summarized below.

OVERALL RESULTS

(\$ in millions, except per share amounts)

	Fourth-Quarter			Full-Year		
	2023	2022	Change	2023	2022	Change
Revenues	\$ 14,249	\$ 24,290	(41%)	\$ 58,496	\$ 100,330	(42%)
Reported ⁽²⁾ Net Income/(Loss)	(3,369)	4,995	*	2,119	31,372	(93%)
Reported ⁽²⁾ Diluted EPS/(LPS)	(0.60)	0.87	*	0.37	5.47	(93%)
Adjusted ⁽³⁾ Income	593	6,551	(91%)	10,501	37,717	(72%)
Adjusted ⁽³⁾ Diluted EPS	0.10	1.14	(91%)	1.84	6.58	(72%)

* Indicates calculation not meaningful.

REVENUES

(\$ in millions)

	Fourth-Quarter				Full-Year			
	2023	2022	% Change		2023	2022	% Change	
			Total	Oper.			Total	Oper.
Global Biopharmaceuticals Business (Biopharma)	\$ 13,867	\$ 23,922	(42%)	(42%)	\$ 57,186	\$ 98,988	(42%)	(41%)
Primary Care	6,986	17,348	(60%)	(60%)	30,589	73,023	(58%)	(57%)
Specialty Care	3,949	3,566	11%	11%	14,970	13,833	8%	11%
Oncology	2,932	3,007	(3%)	(2%)	11,627	12,132	(4%)	(3%)
Business Innovation	\$ 382	\$ 368	4%	2%	\$ 1,310	\$ 1,342	(2%)	(2%)

	\$			
TOTAL REVENUES	\$ 14,249	\$ 24,290 (41%) (42%)	\$ 58,496	100,330 (42%) (41%)

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, an 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. The prior period has been revised to conform to the current period presentation.

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 full-year 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:
 - \$10.7 billion invested in internal research and development projects, and
 - Approximately \$43.8 billion invested in completed business development transactions, net of cash acquired, including approximately \$43 billion for the acquisition of Seagen Inc.
- Returning capital directly to shareholders through \$9.2 billion of cash dividends, or \$1.64 per share of common stock.

No share repurchases were completed in 2023. As of January 30, 2024, Pfizer's remaining share repurchase authorization is \$3.3 billion. Current financial guidance does not anticipate any share repurchases in 2024.

For the fourth quarter of 2023, basic weighted-average shares outstanding of 5,647 million were used to calculate Reported⁽²⁾ LPS and diluted weighted-average shares outstanding of 5,692 million were used to calculate Adjusted⁽³⁾ diluted EPS.

2024 FINANCIAL GUIDANCE⁽⁵⁾

Pfizer expects full-year 2024 revenues⁽²⁾ to be in the range of \$58.5 to \$61.5 billion, which includes approximately \$8 billion in anticipated revenues for Comirnaty⁽¹⁾ and Paxlovid (approximately \$5 billion and \$3 billion, respectively), approximately \$3.1 billion in anticipated revenues from Seagen and approximately \$1 billion related to the reclassification of Pfizer's royalty income from Other (Income)/Deductions into the Revenue line.

Including the contribution from Seagen and excluding revenues from Comirnaty⁽¹⁾ and Paxlovid, Pfizer expects to achieve full-year 2024 operational revenue growth of 8% to 10% compared to 2023 revenues. Excluding revenues from Comirnaty⁽¹⁾ and Paxlovid and the expected contribution from Seagen, Pfizer expects to achieve full-year 2024 operational revenue growth of 3% to 5% compared to 2023 revenues. While the company will begin reporting royalty income in the revenue line in 2024, for growth rate purposes, the company has included royalty income in revenues in both 2023 and 2024. Consequently, there is no operational revenue growth attributable to the reclassification of royalty income.

Including the impact of Seagen, Pfizer anticipates full-year 2024 Adjusted⁽³⁾ SI&A expenses to be in the range of \$13.8 billion to \$14.8 billion and full-year 2024 Adjusted⁽³⁾ R&D expenses to be in the range of \$11.0 to \$12.0 billion. Consequently, total 2024 Adjusted⁽³⁾ SI&A and R&D expenses are expected to be in the range of \$24.8 to \$26.8 billion. This range reflects an anticipated decline of approximately \$4 billion by the end of 2024 versus the midpoint of Pfizer's SI&A and R&D expense guidance provided on August 1, 2023, solely driven by Pfizer's cost realignment program, partially offset by the impact of Seagen.

2024 Adjusted⁽³⁾ diluted EPS is anticipated to be in a range of \$2.05 to \$2.25, which primarily reflects:

- Expected operational revenue growth of 8% to 10% compared to 2023 revenues, excluding Comirnaty⁽¹⁾ and Paxlovid and including the impact of Seagen; and
- Anticipated operating margin improvement from the company's cost realignment activities; partially offset by
- An expected \$0.40 dilutive impact related to the Seagen acquisition, which is predominantly driven by costs to finance the transaction.

Pfizer's 2024 financial guidance⁽⁵⁾, including the impact of certain significant factors, is presented below.

	2023 Results	2024 Legacy Pfizer Guidance	Anticipated Impact of Royalty Income Reclass Included in 2024 Guidance	Anticipated 2024 Seagen Impact Included in 2024 Guidance	2024 Financial Guidance⁽⁵⁾
Revenues (\$ in billions)	\$58.5	\$54.5 to \$57.5	\$1.0	\$3.1	\$58.5 to \$61.5
Adjusted⁽³⁾ SI&A Expenses (\$ in billions)	\$14.4				\$13.8 to \$14.8
Adjusted⁽³⁾ R&D Expenses (\$ in billions)	\$10.6				\$11.0 to \$12.0
Effective Tax Rate on Adjusted⁽³⁾ Income	9.0%				~15.0%
Adjusted⁽³⁾ Diluted EPS	\$1.84	\$2.45 to \$2.65	-	\$(0.40)	\$2.05 to \$2.25

Financial guidance for Adjusted⁽³⁾ diluted EPS is calculated using approximately 5.75 billion weighted average shares outstanding and assumes no share repurchases in 2024.

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

Fourth-quarter 2023 revenues totaled \$14.2 billion, a decrease of \$10.0 billion, or 41%, compared to the prior-year quarter, reflecting an operational decline of \$10.1 billion, or 42%, primarily due to a significant decrease in Comirnaty⁽¹⁾ and Paxlovid revenues globally, as well as a de minimis impact of foreign exchange. Excluding contributions from Comirnaty⁽¹⁾ and Paxlovid, company revenues grew \$934 million, or 8%, operationally.

Fourth-quarter 2023 Comirnaty⁽¹⁾ revenues declined \$6.1 billion, or 54%, operationally compared with the prior-year quarter, largely driven by lower U.S. government contracted deliveries following the transition to traditional U.S. commercial market sales, which began in September 2023, and by lower contracted deliveries and demand in international markets.

Fourth-quarter 2023 Paxlovid revenues declined \$5.0 billion, to \$(3.1) billion, compared with the prior-year quarter, primarily driven by a non-cash revenue reversal of \$3.5 billion recorded in the fourth quarter of 2023, of which a portion was associated with sales recorded in 2022, related to the expected return of an estimated 6.5 million treatment courses of Emergency Use Authorization (EUA)-labeled U.S. government inventory; partially offset by sales under traditional commercial markets following transition, primarily in the U.S.

Excluding contributions from Comirnaty⁽¹⁾ and Paxlovid, fourth-quarter 2023 operational revenue growth was primarily driven by:

- Abrysvo, which contributed \$515 million in global revenues, driven primarily by launch of the older adult indication in the U.S. in July 2023;
- Vyndaqel family (Vyndaqel, Vyndamax, Vynmac) globally, up 39% operationally, driven largely by continued strong uptake of the transthyretin amyloid cardiomyopathy (ATTR-CM) indication, primarily in the U.S. and developed Europe; and
- Eliquis globally, up 9% operationally, driven primarily by continued oral anti-coagulant adoption and market share gains in the non-valvular atrial fibrillation indication in the U.S. and certain markets in Europe, partially offset by declines due to loss of exclusivity and generic competition in certain international markets;

partially offset primarily by lower revenues for:

- Ibrance globally, down 13% operationally, driven primarily by lower demand globally due to competitive pressure and lower clinical trial purchases in certain international markets; and
- Prevnar family (Prevnar 13 & 20) globally, down 7% operationally, driven primarily by the pediatric indication in emerging markets due to lower demand and unfavorable timing of customer orders.

GAAP Reported⁽²⁾ Statement of Operations Highlights

SELECTED REPORTED⁽²⁾ COSTS AND EXPENSES

(\$ in millions)	Fourth-Quarter				Full-Year			
	2023	2022	% Change		2023	2022	% Change	
			Total Oper.				Total Oper.	
Cost of Sales ⁽²⁾	\$ 7,562	\$ 9,648	(22%)	(24%)	\$ 24,954	\$ 34,344	(27%)	(29%)
Percent of Revenues	53.1%	39.7%	N/A	N/A	42.7%	34.2%	N/A	N/A
SI&A Expenses ⁽²⁾	4,575	4,644	(1%)	(2%)	14,771	13,677	8%	9%
R&D Expenses ⁽²⁾	2,815	3,615	(22%)	(22%)	10,679	11,428	(7%)	(6%)
Acquired IPR&D Expenses ⁽²⁾	73	73	—	—	194	953	(80%)	(80%)
Other (Income)/Deductions—net ⁽²⁾	(480)	(846)	(43%)	(51%)	(835)	217	*	*
Effective Tax Rate on Reported ⁽²⁾ Income/(Loss)	19.2%	4.4%			(105.4%)	9.6%		

* Indicates calculation not meaningful.

Fourth-quarter 2023 Cost of Sales⁽²⁾ as a percentage of revenues increased by 13.4 percentage points compared with the prior-year quarter, driven primarily by the \$3.5 billion non-cash Paxlovid revenue reversal; unfavorable changes in sales mix, primarily due to lower sales of Paxlovid and Comirnaty⁽¹⁾; and the unfavorable impact of foreign exchange.

Fourth-quarter 2023 SI&A Expenses⁽²⁾ decreased 2% operationally compared with the prior-year quarter, driven primarily by a decrease in marketing and promotional expenses for Paxlovid, a lower provision for U.S. healthcare reform fees related to Paxlovid and Comirnaty⁽¹⁾, and lower compensation-related expenses, partially offset by increases in marketing and promotional expenses, including those related to recently launched and acquired products, as well as increased investments to build new internal marketing capabilities.

Fourth-quarter 2023 R&D Expenses⁽²⁾ decreased 22% operationally compared with the prior-year quarter, driven primarily by lower compensation-related expenses, as well as by lower spending across (i) vaccine programs, (ii) certain acquired assets and (iii) for ongoing rare disease programs.

The unfavorable period-over-period change in Other income—net⁽²⁾ of \$366 million for the fourth quarter of 2023, compared to the fourth quarter of 2022, was driven primarily by higher intangible asset impairment charges, partially offset by an increase in net gains on equity securities.

Pfizer's positive effective tax rate for the fourth quarter of 2023 reflects a tax benefit on a pre-tax Reported⁽²⁾ loss and includes changes in the jurisdictional mix of earnings and the resolution of uncertain tax positions in various markets.

Adjusted⁽³⁾ Statement of Operations Highlights

SELECTED ADJUSTED⁽³⁾ COSTS AND EXPENSES

(\$ in millions)	Fourth-Quarter				Full-Year			
	2023	2022	% Change		2023	2022	% Change	
			Total	Oper.			Total	Oper.
Adjusted ⁽³⁾ Cost of Sales	\$ 7,265	\$ 9,475	(23%)	(26%)	\$ 23,988	\$ 34,096	(30%)	(31%)
Percent of Revenues	51.0%	39.0%	N/A	N/A	41.0%	34.0%	N/A	N/A
Adjusted ⁽³⁾ SI&A Expenses	4,471	4,414	1%	1%	14,446	13,049	11%	12%
Adjusted ⁽³⁾ R&D Expenses	2,770	3,610	(23%)	(24%)	10,568	11,409	(7%)	(7%)
Adjusted ⁽³⁾ Other (Income)/Deductions—net	(815)	(656)	24%	14%	(2,281)	(1,954)	17%	8%
Effective Tax Rate on Adjusted ⁽³⁾ Income/(Loss)	(24.0%)	11.1%			9.0%	11.7%		

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.

FULL-YEAR REVENUE SUMMARY (Full-Year 2023 vs. Full-Year 2022)

Full-year 2023 revenues totaled \$58.5 billion, a decrease of \$41.8 billion, or 42%, compared to full-year 2022, reflecting an operational decline of \$40.8 billion, or 41%, and an unfavorable impact of foreign exchange of \$1.0 billion, or 1%. Excluding contributions from Comirnaty⁽¹⁾ and Paxlovid, revenues for the full-year grew 7% operationally.

The operational revenue decline compared to the prior year was driven primarily by significantly lower global revenues for Comirnaty⁽¹⁾ and Paxlovid and, to a much lesser extent, lower revenues for Ibrance, partially offset by an increase in revenues from Nurtec ODT/Vydura and Oxbryta, which were acquired in the fourth quarter of 2022; revenues from Abrysvo, primarily driven by the launch of the older adult indication in the U.S.; and continued growth from the Vyndaqel family and Eliquis.

RECENT NOTABLE DEVELOPMENTS (Since October 31, 2023)

Product Developments

- **Elrexio (elranatamab-bcmm)** – In December 2023, Pfizer announced the European Commission (EC) granted conditional marketing authorization for Elrexio for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.
- **Padcev (enfortumab vedotin-ejfv)**
 - In January 2024, Pfizer and Astellas Pharma Inc. (Astellas) announced that the European Medicines Agency (EMA) validated for review a Type II variation application for Padcev, an antibody-drug conjugate (ADC), with Keytruda⁽⁸⁾ (pembrolizumab, a PD-1 inhibitor) as a combination therapy for the first-line treatment of adult patients with previously untreated locally advanced or metastatic urothelial cancer (la/mUC). The EMA's Committee for Medicinal Products for Human Use (CHMP), and subsequently the EC, are expected to share their opinions and decisions on the Type II variation application in calendar year 2024.
 - In December 2023, Pfizer and Astellas announced that the FDA approved Padcev with Keytruda⁽⁸⁾ for the treatment of adult patients with la/mUC based on the results from the Phase 3 EV-302 clinical trial. This combination is the first approved to offer an alternative to platinum-containing chemotherapy, the current standard of care in first-line la/mUC.
- **Prevnar 20 (20-valent pneumococcal conjugate vaccine)** – In January 2024, Pfizer announced the CHMP of the EMA adopted a positive opinion, recommending the granting of a marketing authorization for its 20-valent pneumococcal conjugate vaccine candidate for active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents from 6 weeks to less than 18 years of age. The CHMP's positive opinion will now be reviewed by the EC to decide whether to approve the vaccine. This decision is expected in the coming weeks and will apply to all 27 European Union (EU) member states plus Iceland, Liechtenstein and Norway.
- **Talzenna (talazoparib)** – In January 2024, Pfizer announced that the EC approved Talzenna, an oral poly ADP-ribose polymerase (PARP) inhibitor, in combination with Xtandi (enzalutamide), for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. With this approval, Talzenna is now the first and only PARP inhibitor licensed in the EU for use with Xtandi for patients with mCRPC, with or without gene mutations. The approval is valid in all 27 EU member states plus Iceland, Liechtenstein and Norway.

- **Tivdak (tisotumab vedotin-tftv)** – In January 2024, Pfizer and Genmab A/S announced the FDA accepted the supplemental Biologics License Application (sBLA) seeking to convert the accelerated approval of Tivdak, an ADC, to full approval, for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after first-line therapy. The sBLA is supported by efficacy and safety data from the global, randomized, Phase 3 innovaTV 301 trial. The application was granted Priority Review with a Prescription Drug User Fee Act (PDUFA) goal date of May 9, 2024.
- **Velsipity (etrasimod)** – In December 2023, Pfizer announced the EMA’s CHMP adopted a positive opinion for Velsipity, an oral, once-daily, selective sphingosine-1-phosphate (S1P) receptor modulator for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biological agent. The EC will review the CHMP recommendation and is expected to make a final decision in the coming months.
- **Xtandi (enzalutamide)** – In November 2023, Astellas and Pfizer announced the FDA approved a supplemental New Drug Application (sNDA) for Xtandi following FDA expedited development and review programs (Priority Review designation, Fast Track designation, Real-time Oncology Review), based on results from the Phase 3 EMBARK trial. With this approval, Xtandi becomes the first and only androgen receptor signaling inhibitor approved by the FDA for the treatment of patients with nonmetastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR). Patients with nmCSPC with high-risk BCR may be treated with Xtandi with or without a gonadotropin-releasing hormone (GnRH) analog therapy.

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.

- **Danuglipron** – In December 2023, Pfizer announced topline data from the Phase 2b clinical trial investigating its oral glucagon-like peptide-1 receptor agonist (GLP-1RA) candidate danuglipron in adults with obesity and without type 2 diabetes. The study met its primary endpoint demonstrating statistically significant change in body weight from baseline. While the most common adverse events were mild and gastrointestinal in nature consistent with the mechanism, high rates were observed. High discontinuation rates were seen across all doses compared to placebo. No new safety signals were reported, and treatment with danuglipron was not associated with increased incidence of liver enzyme elevation compared to placebo. Future development of danuglipron will be focused on a once-daily formulation, with pharmacokinetic data anticipated in the first half of 2024, which will help to inform a potential path forward.
- **Marstacimab**
 - In December 2023, Pfizer announced the FDA had accepted the company’s Biologics License Application (BLA) for its anti-tissue factor pathway inhibitor (anti-TFPI) candidate marstacimab for individuals living with hemophilia A or hemophilia B without inhibitors to Factor VIII (FVIII) or Factor IX (FIX). A marketing authorization application for marstacimab is also currently under review by the EMA. The FDA has set a PDUFA action date in the fourth quarter of 2024, and a decision from the EC is anticipated by the first quarter of 2025.
 - In December 2023, Pfizer presented results from the pivotal Phase 3 BASIS clinical trial evaluating marstacimab for the treatment of people with severe hemophilia A and moderately severe to severe hemophilia B without inhibitors to FVIII or FIX. Results from the BASIS trial, which were presented at the 2023 American Society of Hematology Annual Meeting and Exposition,

demonstrated a statistically significant and clinically meaningful effect on annualized bleeding rate. The safety profile for marstacimab was consistent with Phase 1/2 results, and treatment was generally well-tolerated in the study. No deaths were reported, and there have been no thromboembolic events or events of consumptive coagulopathy recorded in hemophilia patients in clinical trials investigating marstacimab.

- **Vepdegestrant (ARV-471)** – In December 2023, Arvinas, Inc. and Pfizer presented interim results from the Phase 1b trial evaluating vepdegestrant, a novel oral PROteolysis TArgeting Chimera (PROTAC) estrogen receptor (ER) degrader, in combination with palbociclib (Ibrance). Study data from the combination cohort demonstrated encouraging clinical activity in heavily pre-treated patients with a median of four lines of therapy across disease settings with locally advanced or metastatic ER positive/human epidermal growth factor 2 (HER2) negative (ER+/HER2-) breast cancer. These data were presented in a spotlight presentation at the 2023 San Antonio Breast Cancer Symposium.
- **VLA15 (Lyme Disease Vaccine Candidate)** – In December 2023, Pfizer and Valneva SE announced the completion of recruitment for the Phase 3 VALOR trial evaluating VLA15, an investigational multivalent protein subunit vaccine for Lyme disease. The trial builds on previous positive Phase 1 and 2 trial results and includes both adult and pediatric participants, with the aim to confirm the efficacy, safety, lot consistency and immunogenicity of VLA15. The VALOR trial is expected to be concluded by the end of 2025.

Corporate Developments

- In December 2023, Pfizer announced the completion of its acquisition of Seagen for \$229 per share, in cash. The total fair value of the consideration transferred was \$44 billion (\$43 billion, net of cash acquired). To address U.S. Federal Trade Commission concerns, Pfizer has chosen to irrevocably donate the rights of royalties from sales of Bavencio⁽⁹⁾ (avelumab) in the U.S. to the American Association for Cancer Research. With the addition of Seagen's four in-line medicines, Adcetris (brentuximab vedotin), Padcev (enfortumab vedotin), Tivdak (tisotumab vedotin) and Tukysa (tucatinib), Pfizer's industry-leading Oncology portfolio now includes over 25 approved medicines and biosimilars across more than 40 indications, including nine medicines that are either blockbuster or have the potential to be blockbuster.
- In December 2023, Pfizer announced changes in its commercial organization to incorporate Seagen and improve focus, speed and quality of execution, effective January 1, 2024. Three new organizations have been created, each led by a member of Pfizer's executive leadership team reporting to Dr. Albert Bourla, Chairman and Chief Executive Officer: (1) the Pfizer Oncology Division, which brings together U.S. oncology commercial operations from both Pfizer and Seagen and is led by Chris Boshoff, M.D., Ph.D., Chief Oncology Officer, Executive Vice President, who also leads Pfizer's newly combined global oncology R&D operations; (2) the Pfizer U.S. Commercial Division, led by Aamir Malik, Chief U.S. Commercial Officer, Executive Vice President; and (3) the Pfizer International Commercial Division, led by Alexandre de Gernay, who has joined Pfizer as Chief International Commercial Officer, Executive Vice President.

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/Q4-2023-PFE-Earnings-Release>

(Note: If clicking on the above link does not open a new webpage, 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), Comirnaty (COVID-19 Vaccine, mRNA, 2023-2024 Formula), the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula), Comirnaty Original/Omicron BA.1, Comirnaty Original/Omicron BA.4/BA.5 and Comirnaty XBB.1.5. “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 \$33 million for full-year 2023 and \$188 million for full-year 2022.
- (2) Revenues is defined as revenues in accordance with U.S. generally accepted accounting principles (GAAP). Reported net income/(loss) and its components are defined as net income/(loss) attributable to Pfizer Inc. common shareholders and its components in accordance with U.S. GAAP. Reported diluted earnings per share (EPS) and reported diluted loss per share (LPS) are defined as diluted EPS or LPS 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 fourth quarter and full-year 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/(loss) and its components and diluted EPS/(LPS)⁽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) Significant one-time impacts to Reported⁽²⁾ and Adjusted⁽³⁾ diluted EPS/LPS:
- Full-year 2023 Reported⁽²⁾ and Adjusted⁽³⁾ diluted EPS were significantly impacted by \$5.6 billion of non-cash COVID product inventory write-offs and related charges in third-quarter 2023 and by a \$3.5 billion non-cash Paxlovid revenue reversal in fourth-quarter 2023, which together unfavorably impacted Reported⁽²⁾ and Adjusted⁽³⁾ diluted EPS by \$(1.36).
 - Fourth-quarter 2023 Reported⁽²⁾ and Adjusted⁽³⁾ diluted LPS/EPS were significantly impacted by a \$3.5 billion non-cash Paxlovid revenue reversal in fourth quarter 2023, which unfavorably impacted Reported⁽²⁾ and Adjusted⁽³⁾ diluted LPS/EPS by approximately \$(0.54).

- (5) 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 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 2024 reflects the following:

- Does not assume the completion of any business development transactions not completed as of December 31, 2023.
 - An anticipated immaterial impact in fiscal-year 2024 of recent and expected generic and biosimilar competition for certain products that have recently lost patent protection or that are anticipated to lose patent protection.
 - Exchange rates assumed are actual rates at mid-November 2023. Financial guidance reflects the anticipated unfavorable impact of approximately \$0.3 billion on revenues and approximately \$0.01 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 2023.
 - Guidance for Adjusted⁽³⁾ diluted EPS assumes diluted weighted-average shares outstanding of approximately 5.75 billion shares, and assumes no share repurchases in 2024.
- (6) 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 fourth quarter and full year for U.S. subsidiaries reflects the three and twelve months ended on December 31, 2023 and December 31, 2022, while Pfizer's fourth quarter and full year for subsidiaries operating outside the U.S. reflects the three and twelve months ended on November 30, 2023 and November 30, 2022.
- (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) Keytruda is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

(9) Bavencio is a registered trademark of Merck KGaA.

DISCLOSURE NOTICE: Except where otherwise noted, the information contained in this earnings release and the related attachments is as of January 30, 2024. 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, including financial guidance and projections; reorganizations; business plans, strategy, goals 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, including patient demand, market size and utilization rates and growth, performance, timing of exclusivity and potential benefits; strategic reviews; capital allocation objectives; an enterprise-wide cost realignment program, which we launched in October 2023 (including anticipated costs, savings and potential benefits); dividends and share repurchases; plans for and prospects of our acquisitions, dispositions and other business development activities, including our recent acquisition of Seagen, and our ability to successfully capitalize on growth opportunities and prospects; manufacturing and product supply; our ongoing efforts to respond to COVID-19, including our plans and expectations regarding 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. Given their forward-looking nature, these statements involve substantial risks, uncertainties and potentially inaccurate assumptions and we cannot assure that any outcome expressed in these forward-looking statements will be realized in whole or in part. 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. Pfizer’s financial guidance is based on estimates and assumptions that are subject to significant uncertainties.

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; uncertainties regarding the ability to obtain, and the scope of, recommendations by technical or advisory committees; and the timing of, and ability to obtain, pricing approvals and product launches, all of which could impact the availability or commercial potential of our products and product candidates;

- 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;
- the success and impact of external business development activities, such as the recent acquisition of Seagen, 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 further 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 or partnered 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 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 as the market for COVID-19 products becomes more endemic and seasonal, demand for any of our COVID-19 products has and may continue to be reduced or not meet expectations, or may no longer exist, which has and may continue to lead to reduced revenues, excess inventory on-hand and/or in the channel which, for Paxlovid and Comirnaty, has resulted in significant inventory write-offs in 2023 and could continue to result in inventory write-offs or other unanticipated charges; challenges related to the transition to the commercial market for our COVID-19 products; uncertainties related to the public's demand for vaccines, boosters and COVID-19 treatments; risks related to our ability to accurately forecast and 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 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 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, or any potential future vaccine or vaccine candidates (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 vaccine or vaccine candidates, 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 any 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 competitive products that may be superior in terms of efficacy, safety, affordability, convenience, or a number of other competitive factors; risks related to the availability or cost of raw materials to manufacture or test any such products; challenges related to our vaccine's formulation and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by us; 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 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 modified; 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, Paxlovid or any future COVID-19 product candidates,

- including challenges driven by misinformation or disinformation, access, concerns about clinical data integrity, or prescriber and pharmacy education; 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 currency devaluations and monetary policy actions in countries experiencing high inflation or deflation 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, vaccines or other products in the pharmaceutical supply chain;
 - any significant issues related to the outsourcing of certain operational and staff functions to third parties;
 - any significant issues related to our JVs and other third-party business arrangements, including modifications related to supply agreements or other contracts with customers including governments or other payors;
 - 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 or interest rate fluctuations, 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, sanctions and/or other restrictive government actions, changes in intellectual property legal protections and remedies, unstable governments and legal systems and inter-governmental disputes;
 - the impact of disruptions related to climate change and natural disasters, including uncertainties related to the impact of the tornado at our manufacturing facility in Rocky Mount, NC in 2023;
 - any changes in business, political and economic conditions due to actual or threatened terrorist activity, geopolitical instability, political or civil unrest or military action, including the ongoing conflicts between Russia and Ukraine and in the Middle East and the resulting economic or other consequences;
 - 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, organizational disruption, adverse effects on employee morale, retention issues or other unintended consequences;
 - 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 reduction or cost control efforts 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 biopharmaceutical 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, medical regulation, environmental protections, 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 without limitation, those related to actual or alleged environmental contamination;
- the risk and impact of an adverse decision or settlement and risk related to the 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. generally effective in most jurisdictions since January 1, 2024 and potential changes to existing tax law by the current U.S. Presidential administration and Congress, including the proposed “Tax Relief for American Families and Workers Act of 2024”;

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;
- risks and challenges related to the use of artificial intelligence-based software;
- 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.

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 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.

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