



NEWS RELEASE

# Moderna Provides Business and Pipeline Updates at 42nd Annual J.P. Morgan Healthcare Conference

1/8/2024

Company announces product sales for 2023 of approximately \$6.7 billion (unaudited); U.S. COVID-19 market share season to date increased to 48% in 2023, up from 37% in 2022

Company reiterates 2024 expected product sales of approximately \$4 billion, planned return to sales growth in 2025 and expectation to break even in 2026 through product launches and disciplined investment

Company highlights nine late-stage programs with anticipated milestones in 2024 and 2025

CAMBRIDGE, MA / ACCESSWIRE / January 8, 2024 / Moderna, Inc. (NASDAQ:MRNA) today announced business updates and progress on the Company's pipeline of transformative mRNA medicines. Moderna enters 2024 with 45 therapeutic and vaccine programs, nine of which are in late-stage development.

"In 2023, we achieved \$6.7 billion in product sales and resized our COVID-19 manufacturing footprint for the endemic setting. Our team significantly increased our COVID-19 market share to 48% in the U.S.," said Stéphane Bancel, Chief Executive Officer of Moderna. "We are preparing for the launch of Moderna's second product, our RSV vaccine. 2024 is going to be an exciting year for the Company with multiple milestones across our nine late-stage programs. Through these product launches, we are focused on returning to sales growth in 2025."

Jamey Mock, Chief Financial Officer of Moderna, will present an update on the Company and its pipeline of mRNA development programs on Monday, January 8th, 2024, at 3:45 p.m. PT/6:45 p.m. ET at the 42nd Annual J.P. Morgan Healthcare Conference. A live webcast of both the presentation and the question-and-answer session will be



available under "Events and Presentations" in the Investors section of Moderna's website at [investors.modernatx.com](https://investors.modernatx.com). A replay of the webcast will be archived on Moderna's website for at least 30 days following the presentation.

### Summary of Financial Updates

2023 financial updates: Moderna achieved 2023 COVID-19 vaccine sales of approximately \$6.7 billion (unaudited). This includes approximately \$6.1 billion of COVID-19 vaccine sales, and recognition of approximately \$0.6 billion of deferred revenue related to the Company's efforts with GAVI, The Vaccine Alliance. Cash, cash equivalents and investments at year-end 2023 were in excess of \$13 billion. Full financial details will be reported on the Company's earnings call on February 22, 2024.

2024 - 2026 financial framework: The Company expects its COVID-19 franchise to be profitable in its anticipated sales scenarios for 2024 and beyond. Moderna continues to project approximately \$4 billion in product sales in 2024, mostly in the second half of the year, primarily due to COVID-19 vaccine sales and the launch of its RSV vaccine. The Company anticipates returning to organic sales growth in 2025 and expects to break even in 2026 through product launches and disciplined investment.

### Summary of Upcoming Late-Stage Pipeline Milestones

Moderna expects numerous product milestones in 2024 and 2025 across its vaccines and therapeutics portfolio.

#### Respiratory vaccines:

- Respiratory syncytial virus (RSV) vaccine: Moderna has filed for regulatory approvals for its vaccine for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) and acute respiratory disease (ARD) in adults ages 60 years or older (mRNA-1345). The Company expects regulatory approvals beginning in the first half of 2024. Moderna will enter the RSV market with a strong competitive profile as the only pre-filled syringe product available at the time of launch, along with robust efficacy data, a well-established safety and tolerability profile, and widespread consumer awareness and demand established in 2023.
- Next-generation COVID-19 vaccine: Moderna's next-generation, refrigerator-stable COVID-19 vaccine (mRNA-1283) is currently in its pivotal Phase 3 study. The Company anticipates data from the study in the first half of 2024.
- Seasonal flu vaccine: Moderna's seasonal flu vaccine (mRNA-1010) demonstrated consistently acceptable safety and tolerability across three Phase 3 trials. In the most recent Phase 3 trial (P303), mRNA-1010 met all immunogenicity endpoints, demonstrating higher titers compared to a currently licensed vaccine. mRNA-1010 has also shown higher or comparable titers compared to a currently licensed enhanced vaccine (Fluzone

HD®) in a separate Phase 1/2 study. The Company is in discussions with regulators and intends to file in 2024.

- Seasonal flu + COVID vaccine: Moderna's Phase 3 trial of its combination vaccine against seasonal flu and COVID-19 (mRNA-1083) is fully enrolled. The Company anticipates data from the study in 2024.

Latent and other vaccines:

- Cytomegalovirus (CMV) vaccine: The pivotal Phase 3 study of Moderna's CMV vaccine candidate (mRNA-1647) is fully enrolled and accruing cases, evaluating its efficacy, safety and immunogenicity in the prevention of primary infection in women of childbearing age. The Company anticipates potential efficacy data from the study in 2024.

Oncology therapeutics:

- Individualized Neoantigen Therapy (INT): Moderna continues to demonstrate the potential clinical benefit of its INT program (mRNA-4157). In partnership with Merck, Phase 3 trials continue to enroll in resected high-risk (stage III/IV) melanoma and completely resected stage II, IIIA or IIIB non-small cell lung cancer. Moderna and Merck plan to rapidly expand their clinical studies to additional tumor types in 2024. The Company recently announced results of a three-year analysis of its Phase 2b study evaluating INT in combination with KEYTRUDA®, Merck's anti-PD-1 therapy, in patients with resected high-risk melanoma. Compared to KEYTRUDA alone, this combination continued to show an improvement in recurrence-free survival, reducing the risk of recurrence or death by 49%, as well as in distant metastasis-free survival, reducing the risk of developing distant metastasis or death by 62%.

Rare disease therapeutics:

- Propionic acidemia (PA) & methylmalonic acidemia (MMA): The Company expects to advance its PA (mRNA-3705) and MMA (mRNA-3927) programs into pivotal studies in 2024.

Key 2024 Investor and Analyst Event Dates

- Q4 and FY 2023 Earnings Call: February 22, 2024
- Vaccines Day: March 27, 2024
- R&D Day: September 12, 2024

About Moderna

Moderna is a leader in the creation of the field of mRNA medicine. Through the advancement of mRNA technology, Moderna is reimagining how medicines are made and transforming how we treat and prevent disease for everyone. By working at the intersection of science, technology and health for more than a decade, the company has developed medicines at unprecedented speed and efficiency, including one of the earliest and most effective

COVID-19 vaccines.

Moderna's mRNA platform has enabled the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and autoimmune diseases. With a unique culture and a global team driven by the Moderna values and mindsets to responsibly change the future of human health, Moderna strives to deliver the greatest possible impact to people through mRNA medicines. For more information about Moderna, please visit **modernatx.com** and connect with us on X (formerly Twitter), Facebook, Instagram, YouTube and LinkedIn.

Fluzone® is a registered trademark of Sanofi Pasteur.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp.

#### Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: Moderna's anticipated future revenues, sales growth, profitability and margins; the potential timing for future product approvals and commercial launches; and the advancement of Moderna's pipeline and late-stage programs, including the commencement of additional clinical trials. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those other risks and uncertainties described under the heading "Risk Factors" in Moderna's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the U.S. Securities and Exchange Commission (SEC), and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at **www.sec.gov**. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date of this press release.

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