Moderna Reports Fourth Quarter and Fiscal Year 2023 Financial Results and Provides Business Updates

Posts fourth quarter revenues of $2.8 billion, GAAP net income of $217 million and GAAP diluted EPS of $0.55

Reports full-year revenues of $6.8 billion, GAAP net loss of $(4.7) billion and GAAP diluted EPS of $(12.33); loss primarily driven by mostly non-cash charges of $3.7 billion related to resizing and a tax valuation allowance

Reaffirms 2024 expected product sales of approximately $4 billion

Expects regulatory approvals for its investigational RSV vaccine for older adults beginning in first half of 2024, and anticipates additional key milestones from its late-stage pipeline this year

CAMBRIDGE, MA / ACCESSWIRE / February 22, 2024 / Moderna, Inc. (NASDAQ:MRNA) today reported financial results and provided business updates for the fourth quarter and fiscal year 2023.

"2023 was a year of transition for Moderna as we adapted to the endemic market. At the same time, our development team made significant pipeline advancements across infectious diseases, oncology and rare diseases, while our commercial team increased our COVID-19 market share in the U.S.," said Stéphane Bancel, Chief Executive Officer of Moderna. "We look forward to the anticipated approvals of our RSV vaccine beginning in the first half of the year. With multiple upcoming Phase 3 data readouts in 2024, we remain focused on commercial execution and continued investment in our pipeline with financial discipline."

Recent progress includes:

Commercial Updates

COVID-19: The Company reported $2.8 billion in Spikevax® (COVID-19 vaccine) sales in the fourth quarter of 2023, which includes $0.8 billion of U.S. sales and $2 billion of international sales. This led to $6.7 billion in vaccine sales for fiscal 2023, consistent with the previously communicated financial framework of at least $6 billion.

Moderna achieved 48% cumulative market share[1] in the U.S. retail segment during the fall 2023 COVID season, up from 37% in 2022. Moderna took specific actions in 2023 to transition to a seasonal endemic market including the resizing of its manufacturing footprint to improve cash flow, the flattening of its commercial structure to drive sales execution, and the focusing of its investments toward near-term growth drivers.

The Company is reaffirming its 2024 product sales outlook as it enters the second year of the U.S. commercial endemic COVID market with increased clarity of market size and dynamics. Moderna continues to focus on public health efforts to increase vaccination coverage rates globally for the

[1] Based on information licensed from IQVIA: IQVIA RAPID Weekly Audit for September-December 2023, reflecting estimates of real-world activity. All rights reserved.

2024/2025 season to reduce the substantial burden of COVID-19. The Company is also prioritizing key international markets for greater commercial focus and is participating in the EU Health Emergency and Response Authority's tendering procedure for up to 36 million doses of mRNA COVID-19 vaccines per year for up to four years.

RSV: The Company continues to expect initial regulatory approvals of its RSV vaccine (mRNA-1345) starting in the first half of 2024.

Moderna is well-prepared for the launch of its second respiratory vaccine, which will build upon the success of its commercial efforts in the fall COVID-19 market. The Company is encouraged by early indications of widespread consumer awareness and established demand in the RSV market, which Moderna will enter with a strong competitive profile with robust efficacy data, a well-established safety and tolerability profile, and as the only pre-filled syringe (PFS) product available at the time of launch. The PFS ready-to-use formulation will save pharmacists and clinicians time as well as potentially help reduce administration errors.

The PDUFA (Prescription Drug User Fee Act) action date for mRNA-1345 is May 12, 2024, by which time the Company expects the U.S. FDA's response to its Biologics License Application (BLA). If the outcome is positive, the Company anticipates that the U.S. CDC Advisory Committee on Immunization Practices (ACIP) will include mRNA-1345 on the agenda of its June 26-28 meeting. Assuming that corresponding marketing authorizations would be granted as expected, the Company also plans to launch its RSV vaccine in Australia and Germany in 2024 and other markets in 2025 due to regulatory and tender timing.

Fourth Quarter 2023 Financial Results

Revenue: Total revenue for the fourth quarter of 2023 was $2.8 billion, a decrease from $5.1 billion in the same period in 2022, primarily due to a reduction in sales of the Company's COVID-19 vaccine. Net product sales for the fourth quarter of 2023 were $2.8 billion, representing a 43% decline compared to the same period in 2022, primarily driven by lower sales volume, partially offset by a higher average selling price. Net product sales in the fourth quarter of 2023 include the recognition of $0.6 billion from deferred revenue, related to Gavi, the Vaccine Alliance.

Cost of Sales: Cost of sales for the fourth quarter of 2023 totaled $929 million, which included third-party royalties of $125 million, or 33% of net product sales, compared to 39% of net product sales for the fourth quarter of 2022. In the third quarter of 2023, the Company embarked on a strategic initiative aimed at optimizing the cost structure of its COVID-19 business, with an emphasis on resizing its manufacturing cost structure. The initiative involved scaling down the Company's capacity and commitments with its third-party contract manufacturing organizations (CMOs), reevaluating its raw material inventory levels, and reducing its purchase commitments related to raw materials that were not expected to be consumed before expiration. As a part of this strategic effort during the fourth quarter of 2023, the Company incurred, as expected, additional charges of $169 million, primarily related to the wind-down of certain contract manufacturing operations. Additionally, cost of sales also includes an inventory write-down of $322 million, reflecting revised demand forecasts as the Company adapts to the end-of-season trends.

Research and Development Expenses: Research and development expenses for the fourth quarter of 2023 increased by 16% to $1.4 billion, compared to the same quarter of 2022. The growth in spending

was largely driven by increased clinical manufacturing activities, notably with respect to the Company's RSV vaccine, cytomegalovirus (CMV) vaccine, combination vaccine against flu and COVID-19, as well as its individualized neoantigen therapy. The increase also included an upfront payment of $120 million associated with the strategic research and development collaboration with Immatics.

Selling, General and Administrative Expenses: Selling, general and administrative expenses for the fourth quarter of 2023 increased by 25% to $470 million, in comparison to the fourth quarter of 2022. The growth in spending was primarily due to increased personnel-related costs and commercial and marketing expenses, driven by the expansion of commercial operations, particularly in the U.S. market.

Income Taxes: Income tax benefit for the fourth quarter of 2023 was $147 million, largely attributable to the tax benefits as part of finalizing our 2022 U.S. tax return.

Net Income: Net income was $217 million for the fourth quarter of 2023, compared to $1.5 billion for the fourth quarter of 2022, primarily driven by lower COVID-19 product sales.

Earnings Per Share: Diluted earnings per share was $0.55 for the fourth quarter of 2023, compared to $3.61 for the fourth quarter of 2022.

Full Year 2023 Financial Results

Revenue: Total revenue was $6.8 billion for the full year 2023, compared to $19.3 billion in 2022. The decrease in total revenue for 2023 was mainly due to a decline in sales of the Company's COVID-19 vaccine. Net product sales for 2023 were $6.7 billion, a decrease of 64% from 2022, driven by lower vaccination rates. Net product sales include the recognition of $0.6 billion from deferred revenue, related to Gavi, the Vaccine Alliance.

Cost of Sales: Cost of sales for the full year 2023 was $4.7 billion, or 70% of net product sales, inclusive of third-party royalties of $301 million, inventory write-downs of $2.2 billion, unutilized manufacturing capacity and wind-down costs of $981 million, and losses on firm purchase commitments and cancellation fees of $205 million. Cost of sales includes a total of $1.6 billion, resulting from the Company's strategic initiative to resize its manufacturing cost structure that was launched in the third quarter of 2023. Cost of sales, as a percentage of net product sales, increased by 41 percentage points to 70%, from 29% in 2022. The increase in cost of sales as a percentage of net product sales was primarily due to the strategic initiative and other aforementioned charges (excluding royalties) over lower net product sales, driven by a decline in product demand and increased product seasonality.

Research and Development Expenses: Research and development expenses increased by 47% to $4.8 billion for 2023, compared to 2022. The increase in spending in 2023 was mainly attributable to increases in clinical trial and clinical manufacturing expenses, personnel-related costs, and consulting and outside services, largely driven by the Company's late-stage clinical studies for the RSV vaccine, CMV vaccine, combination vaccine against seasonal influenza and COVID-19, and the individualized neoantigen therapy program, as well as continued development of the Company's pipeline.

Selling, General and Administrative Expenses: Selling, general and administrative expenses increased by 37% to $1.5 billion for 2023, compared to 2022. The increase in spending in 2023 was primarily

attributable to the Company's continued corporate expansion, particularly in the commercial area.

Income Taxes: Income tax provision for the full year 2023 was $772 million, which was primarily driven by a non-cash charge related to a valuation allowance on deferred tax assets.

Net Income (Loss): Net loss for the full year 2023 was $(4.7) billion, compared to a net income of $8.4 billion in 2022.

Earnings (Loss) Per Share: Diluted loss per share for the full year 2023 was $(12.33), compared to a diluted earnings per share of $20.12 in 2022.

Cash Position: Cash, cash equivalents and investments as of December 31, 2023, and December 31, 2022, were $13.3 billion and $18.2 billion, respectively. The decrease in cash position in 2023 was largely attributable to the full year's operating loss and the repurchases of the Company's common stock during the first half of the year.

2024 Financial Framework

Revenue: The Company expects revenue of approximately $4 billion for 2024 from its respiratory franchise.

Cost of Sales: The Company expects cost of sales for 2024 to be approximately 35% of product sales for the year.

Research and Development Expenses: The Company expects full-year 2024 research and development expenses of approximately $4.5 billion, compared to $4.8 billion in 2023.

Selling, General and Administrative Expenses: The Company expects full-year 2024 selling, general and administrative expenses of approximately $1.3 billion, compared to $1.5 billion in 2023.

Income Taxes: The Company anticipates its full-year tax expense to be negligible.

Capital Expenditures: The Company expects capital expenditures for 2024 of approximately $0.9 billion.

Cash and Investments: The Company expects 2024 year-end cash and investments of approximately $9 billion.

Recent Progress and Upcoming Late-Stage Pipeline Milestones

With nine late-stage programs, Moderna continues to advance its pipeline and expects numerous product milestones in 2024 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 regulatory applications are based on positive data from the pivotal ConquerRSV study, a randomized, double-blind, placebo-controlled study of approximately 37,000 adults, 60 years or older. The trial met both its primary efficacy endpoints, with a vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; p<0.0001) against RSV-LRTD as defined by two or more symptoms, and a VE of 82.4% (96.36% CI: 34.8%, 95.3%; p=0.0078) against RSV-LRTD defined by three or more symptoms. Most solicited adverse reactions were mild to moderate, and no cases of Guillain-Barre Syndrome (GBS) have been reported with mRNA-1345 in the Phase 3 RSV trial. These data were published in the *New England Journal of Medicine* in December 2023.

Follow-up data from a Phase 3 RSV study with a median follow-up duration of 8.6 months, with a range of 15 days to 530 days, and including subjects from the Northern and Southern Hemispheres was recently presented at the RSVVW'24 conference. In this supplemental analysis, mRNA-1345 maintained durable efficacy, with sustained VE of 63.3% (95.88% CI: 48.7%, 73.7%) against RSV-LRTD including two or more symptoms. VE was 74.6% (95% CI, 50.7-86.9) against RSV-LRTD with ≥2 symptoms, including shortness of breath and 63.0% (95% CI, 37.3-78.2) against RSV-LRTD including three of more symptoms. The stringent statistical criterion of the study, a lower bound on the 95% CI of >20%, continued to be met for both endpoints. As mentioned above, **the Company expects regulatory approvals beginning 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 standard-dose flu vaccine. mRNA-1010 has also shown higher or comparable titers compared to a currently licensed enhanced flu vaccine (Fluzone HD®) in a separate Phase 1/2 study. **The Company is in ongoing discussions with regulators and intends to file in 2024**.

- Next-generation COVID-19 vaccine: Moderna's Phase 3 study of its next-generation COVID-19 vaccine (mRNA-1283), which is designed to be refrigerator-stable, is fully enrolled. **The Company anticipates data from the study in the first half of 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:

- 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 initiate clinical studies in additional tumor types in 2024.**

  In December 2023, the Company 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%. Additionally, the results of the primary analysis at two-year follow-up of its Phase 2 study were published in *The Lancet*.

  The Company has purchased and started build-out of a manufacturing site in Marlborough, MA, to enable commercial scale of its INT program.

Rare disease therapeutics:

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

Moderna Corporate Updates

- Highlighted the Company's digital and AI strategy and progress at its second Digital Investor Event on November 8, 2023.
- Reviewed the Company's progress and ambitions during its second Environmental, Social and Governance (ESG) Investor Event on December 7, 2023.
- Published Moderna CEO Stéphane Bancel's annual letter to shareholders on January 2, 2024.
- Provided business and pipeline updates at the 42nd Annual J.P. Morgan Healthcare Conference on January 8, 2024.
- Scheduled the Moderna Annual Meeting of Shareholders to be held on Monday, May 6, 2024, at 8:00 a.m. ET.

Company accolades:

- Moderna topped *BioSpace*'s Best Places to Work in Biopharma ranking for the third consecutive year.
- Moderna was named to *Fortune*'s list of World's Most Admired Companies for the first time.
- Stéphane Bancel, Chief Executive Officer of Moderna, was elected to the National Academy of Engineering.

Key 2024 Investor and Analyst Event Dates

- Vaccines Day: March 27 at 9 a.m. ET
- R&D Day: September 12

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on February 22, 2024. To access the live conference call via telephone, please register at the link below. Once registered, dial-in numbers and a unique pin number will be provided. A live webcast of the call will also be available under "Events and Presentations" in the Investors section of the Moderna website.

- **Telephone:** https://register.vevent.com/register/BI0c7f1372a78b427d9f354a2630418034
- **Webcast:** https://investors.modernatx.com

The archived webcast will be available on Moderna's website approximately two hours after the conference call and will be available for one year following the call.

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.

MODERNA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in millions, except per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Revenue:				
Net product sales	$ 2,793	$ 4,859	$ 6,671	$ 18,435
Other revenue[1]	18	225	177	828
Total revenue	2,811	5,084	6,848	19,263
Operating expenses:				
Cost of sales	929	1,918	4,693	5,416
Research and development	1,406	1,211	4,845	3,295
Selling, general and administrative	470	375	1,549	1,132
Total operating expenses	2,805	3,504	11,087	9,843
Income (loss) from operations	6	1,580	(4,239)	9,420
Interest income	103	87	421	200
Other expense, net	(39)	(12)	(124)	(45)
Income (loss) before income taxes	70	1,655	(3,942)	9,575
(Benefit from) provision for income taxes	(147)	190	772	1,213
Net income (loss)	$ 217	$ 1,465	$ (4,714)	$ 8,362
Earnings (loss) per share:				
Basic	$ 0.57	$ 3.81	$ (12.33)	$ 21.26
Diluted	$ 0.55	$ 3.61	$ (12.33)	$ 20.12
Weighted average common shares used in calculation of earnings (loss) per share:				
Basic	381	385	382	394
Diluted	395	405	382	416

[1]Includes grant revenue and collaboration revenue

MODERNA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in millions)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,907	$ 3,205
Investments	5,697	6,697
Accounts receivable, net	892	1,385
Inventory	202	949
Prepaid expenses and other current assets	627	1,195
Total current assets	10,325	13,431
Investments, non-current	4,677	8,318
Property, plant and equipment, net	1,945	2,018
Right-of-use assets, operating leases	713	121
Deferred tax assets	81	982
Other non-current assets	685	988
Total assets	$ 18,426	$ 25,858
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 520	$ 487
Accrued liabilities	1,798	2,101
Deferred revenue	568	2,038
Income taxes payable	63	48
Other current liabilities	66	249
Total current liabilities	3,015	4,923
Deferred revenue, non-current	83	673
Operating lease liabilities, non-current	643	92
Financing lease liabilities, non-current	575	912
Other non-current liabilities	256	135
Total liabilities	4,572	6,735
Stockholders' equity:		
Additional paid-in capital	371	1,173
Accumulated other comprehensive loss	(123)	(370)
Retained earnings	13,606	18,320
Total stockholders' equity	13,854	19,123
Total liabilities and stockholders' equity	$ 18,426	$ 25,858

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in millions)

	Years Ended December 31,	
	2023	2022
Operating activities		
Net (loss) income	$ (4,714)	$ 8,362
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Stock-based compensation	305	226
Depreciation and amortization	621	348
Amortization/accretion of investments	(61)	31
Loss on equity investments, net	35	—
Deferred income taxes	828	(559)
Other non-cash items	7	28
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable, net	493	1,790
Prepaid expenses and other assets	974	(1,699)
Inventory	747	492
Right-of-use assets, operating leases	(605)	21
Accounts payable	13	240
Accrued liabilities	(340)	612
Deferred revenue	(2,060)	(4,157)
Income taxes payable	15	(828)
Operating lease liabilities	551	(14)
Other liabilities	73	88
Net cash (used in) provided by operating activities	(3,118)	4,981
Investing activities		
Purchases of marketable securities	(3,760)	(11,435)
Proceeds from maturities of marketable securities	5,575	3,151
Proceeds from sales of marketable securities	3,206	3,548
Purchases of property, plant and equipment	(707)	(400)
Acquisition of business, net of cash acquired	(85)	—
Investment in convertible notes and equity securities	(23)	(40)
Net cash provided by (used in) investing activities	4,206	(5,176)
Financing activities		
Proceeds from issuance of common stock through equity plans	46	65
Repurchase of common stock, including excise tax	(1,153)	(3,329)
Changes in financing lease liabilities	(270)	(184)
Net cash used in financing activities	(1,377)	(3,448)
Net decrease in cash, cash equivalents and restricted cash	(289)	(3,643)
Cash, cash equivalents and restricted cash, beginning of year	3,217	6,860
Cash, cash equivalents and restricted cash, end of period	$ 2,928	$ 3,217

Spikevax® is a registered trademark of Moderna.
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 approval and launch of its RSV vaccine in 2024 and 2025, market dynamics, and its competitive profile; Moderna's 2024 financial framework and anticipated performance, including expected revenues; the potential for Moderna to launch up to 15 products in the next five years; anticipated milestones for Moderna's pipeline programs in 2024; and the future profitability of Moderna's COVID-19 vaccine franchise. In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “could,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. 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, among others, those 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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