Moderna Reports First Quarter 2024 Financial Results and Provides Business Updates

Reports first quarter revenues of $167 million, GAAP net loss of $1.2 billion and GAAP diluted EPS of $(3.07)

Prepares for launches of RSV vaccine and Spikevax® 2024-2025 formula; reaffirms 2024 expected product sales of approximately $4 billion

Initiated three new clinical studies evaluating Moderna's investigational individualized neoantigen therapy in combination with Merck's Keytruda® for treatment of patients with bladder cancer, kidney cancer and cutaneous squamous cell carcinoma

Advanced three new vaccine programs (Epstein-Barr virus, Varicella-Zoster virus, norovirus) toward Phase 3 clinical trials as announced at Vaccines Day investor event

CAMBRIDGE, MA / ACCESSWIRE / May 2, 2024 / Moderna, Inc. (NASDAQ:MRNA) today reported financial results and provided business updates for the first quarter of 2024.

"As we anticipate the launches of our Spikevax 2024-2025 formula and RSV vaccine, we are exercising financial discipline and have intensified our focus on building and utilizing AI technologies to further streamline operations and enhance productivity," said Stéphane Bancel, Chief Executive Officer of Moderna. "With 10 late-stage programs, and additional new programs advancing toward pivotal studies, we continue to expect numerous product milestones this year across our vaccines and therapeutics portfolio. This is the start of a banner year for our vaccine platform as we continue to advance mRNA medicines for patients. This is just the beginning."

Recent progress includes:

Commercial Updates

COVID-19: The Company reported $167 million in Spikevax (COVID-19 vaccine) sales in the first quarter of 2024, which includes $100 million of U.S. sales and $67 million of international sales.

In the U.S., the Company is reaffirming its 2024 product sales outlook as it enters the second year of the commercial endemic COVID market. Moderna's focus is on working with public health officials, health care providers and pharmacies to increase vaccination coverage rates to reduce the substantial burden of COVID-19. Moderna is also working with the U.S. FDA and regulators to align the timing of flu and COVID-19 vaccine approvals, which is expected to result in higher vaccination uptake if vaccines are available sooner and offered at the same time as the flu shot.

In the European Union, Moderna 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.

In the Rest of World, the Company is prioritizing markets for greater commercial focus and in April announced a contract with the Ministry of Health in Brazil (Ministério da Saúde) to supply 12.5 million

mRNA COVID-19 vaccines as an integral part of Brazil's 2024 national vaccination campaign against COVID-19.

RSV: The Company anticipates initial regulatory approvals of its RSV vaccine (mRNA-1345) beginning in the first half of 2024.

Moderna is targeting fall 2024 for its U.S. RSV vaccine launch, 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 clinical efficacy data, a well-established safety and tolerability profile for its mRNA technology, and as the only pre-filled syringe (PFS) product available.

The PFS ready-to-use formulation will save pharmacists and clinicians time, potentially alleviating wait times and reducing the burden on pharmacy staff. In a study funded by Moderna, the PFS presentation was three to four times more efficient than vaccines requiring reconstitution, measured in doses per hour and based on mean time of preparation.

First Quarter 2024 Financial Results

Revenue: Total revenue for the first quarter of 2024 was $167 million, compared to $1.9 billion in the same period in 2023. The decline was primarily due to reduced sales of the Company's COVID-19 vaccine. Net product sales for the first quarter of 2024 were $167 million, representing a 91% decline compared to the same period in 2023. This decline aligns with the anticipated transition to a seasonal COVID-19 vaccine market; in the prior year period, the Company recognized revenue primarily from delivered doses deferred from 2022.

Cost of Sales: Cost of sales for the first quarter of 2024 totaled $96 million, which included third-party royalties of $8 million, inventory write-downs of $30 million, and unutilized manufacturing capacity and winddown costs of $27 million. Cost of sales for the first quarter of 2024 decreased by $696 million, or 88%, compared to the same period in 2023. Cost of sales as a percentage of net product sales was 58% for the first quarter of 2024, compared to 43% for the first quarter of 2023. The decrease in cost of sales in 2024 was primarily driven by lower sales volume coupled with reduced unutilized manufacturing capacity, inventory write-downs and losses on firm purchase commitments and related cancellation fees. Conversely, the increase in cost of sales as a percentage of net product sales in 2024 was driven by the lower sales level compared to the prior year.

Research and Development Expenses: Research and development expenses for the first quarter of 2024 decreased by 6% to $1.1 billion, compared to the same quarter of 2023. This reduction was primarily due to the absence of upfront collaboration payments being made in 2024. The upfront payments made in the first quarter of 2023 were related to the Company's strategic collaborations with Generation Bio and Life Edit Therapeutics. Additionally, there was a decrease in clinical development and manufacturing expenses, driven by lower spending on clinical trials for the Company's COVID-19, RSV and seasonal flu programs, which aligns with its planned trial schedules. These decreases were partially offset by higher personnel-related costs, resulting from an increased headcount in the research and development functions.

Selling, General and Administrative Expenses: Selling, general and administrative expenses for the first quarter of 2024 decreased by 10% to $274 million, compared to the first quarter of 2023. This

decrease is a result of cost discipline and the efficiencies resulting from investments the Company made in foundational capabilities over the last year, which allowed for a significant reduction of purchased services and the use of external consultants. The Company continues to invest in digital and commercial capabilities and has intensified its focus on building and utilizing AI technologies to further streamline operations and enhance productivity.

Income Taxes: Income tax expense for the first quarter of 2024 was $10 million, in contrast to an income tax benefit of $384 million in the same period last year. The shift primarily resulted from the continued application of a valuation allowance on the majority of the Company's deferred tax assets, first established in the third quarter of 2023. The Company only maintained a valuation allowance on certain state deferred tax assets prior to the third quarter of 2023.

Net Income (Loss): Net loss was $(1.2) billion for the first quarter of 2024, compared to net income of $79 million for the first quarter of 2023.

Earnings (Loss) Per Share: Diluted loss per share was $(3.07) for the first quarter of 2024, compared to diluted earnings per share of $0.19 for the first quarter of 2023.

Cash Position: Cash, cash equivalents and investments as of March 31, 2024, were $12.2 billion, compared to $13.3 billion as of December 31, 2023. The decrease in the Company's cash position during the first quarter of 2024 was largely attributable to research and development expenses and operating activities.

2024 Financial Framework

Expectations for full year 2024 remain consistent with prior expectations.

Revenue: The Company reaffirms its 2024 expected revenue of approximately $4 billion from its respiratory franchise, and now expects approximately $0.3 billion in net sales in the first half of the year, reflecting the seasonality of the respiratory business.

Cost of Sales: Cost of sales is expected to be approximately 35% of product sales for the year.

Research and Development Expenses: Full-year 2024 research and development expenses are anticipated to be approximately $4.5 billion.

Selling, General and Administrative Expenses: Selling, general and administrative expenses for 2024 are projected to be approximately $1.3 billion.

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

Capital Expenditures: Capital expenditures for 2024 are expected to be approximately $0.9 billion.

Cash and Investments: Year-end cash and investments for 2024 are projected to be approximately $9 billion.

Recent Progress and Upcoming Late-Stage Pipeline Milestones

With 10 late-stage programs, and additional new programs advancing toward pivotal studies, Moderna continues to advance its pipeline and expects numerous product milestones in 2024 across its vaccines and therapeutics portfolio. Late-stage includes eight programs that have progressed to Phase 3 clinical studies and two rare disease programs that are moving toward registrational studies.

Respiratory vaccines:

- Respiratory syncytial virus (RSV) vaccine: Moderna's RSV vaccine candidate (mRNA-1345) is in an ongoing Phase 2/3 clinical trial, ConquerRSV. Based on positive data from the study, Moderna has filed for regulatory approvals for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) and acute respiratory disease (ARD) in adults over 60 years of age. As mentioned above, **the Company is awaiting regulatory approvals and the U.S. ACIP recommendation in 2024.**

  At its Vaccines Day event in March, Moderna announced the initiation of multiple Phase 3 expansion studies of its RSV vaccine in adults over 50 years of age to evaluate co-administration and revaccination. Additional trials (Phase 1 - Phase 3) have been initiated for high-risk adults, as well as maternal and pediatric populations. **Interim data from these studies could be available as early as 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. In an older adult extension study of P303, mRNA-1010 is being studied against high dose Fluzone HD®; the trial is fully enrolled. **The Company is in ongoing discussions with regulators and intends to file in 2024**.

- Next-generation COVID-19 vaccine: A recent announcement of positive interim results from the NEXTCove Phase 3 trial showed that Moderna's next-generation COVID-19 vaccine (mRNA-1283) elicited a higher immune response against both the Omicron BA.4/BA.5 and original virus strains of SARS-CoV-2 compared to Moderna's licensed COVID-19 vaccine (mRNA-1273.222). The next-generation vaccine is designed to be refrigerator-stable and paves the way for a combination vaccine against influenza and COVID-19 (mRNA-1083). This is Moderna's fourth infectious disease vaccine program with positive Phase 3 data. **The Company is engaging with regulators on next steps.**

- 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 first interim analysis for the evaluation of vaccine efficacy is **expected as early as the end of 2024**.

- Epstein-Barr virus (EBV) vaccine: Moderna's EBV vaccine candidate for the prevention of infectious mononucleosis (mRNA-1189) showed positive immunogenicity and safety data in a Phase 1 study. **The Company is advancing this candidate toward pivotal development.**

- Varicella-Zoster virus (VZV) vaccine: In a Phase 1/2 trial, Moderna's VZV vaccine candidate for the prevention of shingles (mRNA-1468) elicited comparable or higher T cell responses relative to Shingrix. **The Company is advancing toward a pivotal Phase 3 trial.**

- Herpes simplex virus (HSV) vaccine: The Phase 1/2 study of Moderna's HSV vaccine candidate (mRNA-1608) is fully enrolled.

- Norovirus vaccine: Moderna's vaccine candidate for the prevention of norovirus (mRNA-1403) showed positive immunogenicity and safety data in a Phase 1 study. **The Company is advancing toward a pivotal Phase 3 trial.**

Oncology therapeutics:

- Individualized Neoantigen Therapy (INT): Moderna continues to demonstrate the potential clinical benefit of its INT program (mRNA-4157). In partnership with Merck, two Phase 3 trials in resected high-risk (stage III/IV) melanoma and completely resected stage II, IIIA or IIIB non-small cell lung cancer are ongoing.

  Moderna and Merck have initiated three new randomized clinical studies in additional tumor types in 2024, including a Phase 2 adjuvant treatment in patients with renal cell carcinoma, or kidney cancer; a Phase 2 adjuvant treatment in patients with high-risk muscle-invasive bladder cancer; and a Phase 2/3 neoadjuvant and adjuvant treatment in patients with cutaneous squamous cell carcinoma, the second most common form of skin cancer.

Rare disease and other therapeutics:

- Propionic acidemia (PA) & methylmalonic acidemia (MMA) therapeutics: Interim data for a first-in-human, Phase 1/2, open-label, dose optimization study and extension study, evaluating the safety and efficacy of an investigational mRNA therapy for PA (mRNA-3927), was published in *Nature*. The Company expects to advance its PA and MMA (mRNA-3705) programs **into registrational studies in 2024**.

- PD-L1 therapeutic: Following a strategic review, and as a result of its decision to prioritize investments in other programs, Moderna is discontinuing development of its preclinical PD-L1 program (mRNA-6981), and is no longer evaluating other mRNA candidates in this area.

Moderna Corporate Updates

- Announced the advancement of multiple vaccine programs to late-stage clinical trials at its fifth Vaccines Day Investor Event on March 27, 2024.
- Announced a development and commercialization funding agreement on March 27, 2024, with Blackstone Life Sciences for up to $750 million to advance Moderna's flu program.
- Announced a new collaboration with OpenAI to advance mRNA medicine using generative AI.
- Entered into a non-exclusive intellectual property licensing agreement with an upfront payment and low double-digit royalty on the net sales of a COVID-19 product from a pharmaceutical company in the territory of Japan.
- Agreed with Metagenomi to terminate gene editing collaboration as Moderna continues to strategically prioritize its research and development investments.
- The Moderna Annual Meeting of Shareholders will be held on May 6, 2024, at 8:00 a.m. ET.

Company Accolade:

- Moderna was named for the first time to the LinkedIn Top Companies list of the best workplaces to grow a career in the U.S.

Key 2024 Investor and Analyst Event Dates

- ASCO Investor Event: June 3
- 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 May 2, 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/BI4b70dc922b874480847b6928c1fb9579
- **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 March 31,	
	2024	2023
Revenue:		
Net product sales	$ 167	$ 1,828
Other revenue[1]	—	34
Total revenue	167	1,862
Operating expenses:		
Cost of sales	96	792
Research and development	1,063	1,131
Selling, general and administrative	274	305
Total operating expenses	1,433	2,228
Loss from operations	(1,266)	(366)
Interest income	120	109
Other expense, net	(19)	(48)
Loss before income taxes	(1,165)	(305)
Provision for (benefit from) income taxes	10	(384)
Net (loss) income	$ (1,175)	$ 79
(Loss) earnings per share:		
Basic	$ (3.07)	$ 0.20
Diluted	$ (3.07)	$ 0.19
Weighted average common shares used in calculation of (loss) earnings per share:		
Basic	382	386
Diluted	382	405

[1]Includes grant revenue and collaboration revenue

MODERNA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in millions)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 2,051	$ 2,907
Investments	6,472	5,697
Accounts receivable, net	137	892
Inventory	295	202
Prepaid expenses and other current assets	645	627
Total current assets	9,600	10,325
Investments, non-current	3,638	4,677
Property, plant and equipment, net	2,063	1,945
Right-of-use assets, operating leases	697	713
Deferred tax assets	81	81
Other non-current assets	650	685
Total assets	$ 16,729	$ 18,426
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 183	$ 520
Accrued liabilities	1,396	1,798
Deferred revenue	559	568
Income taxes payable	52	63
Other current liabilities	190	66
Total current liabilities	2,380	3,015
Deferred revenue, non-current	58	83
Operating lease liabilities, non-current	637	643
Financing lease liabilities, non-current	575	575
Other non-current liabilities	262	256
Total liabilities	3,912	4,572
Stockholders' equity:		
Additional paid-in capital	487	371
Accumulated other comprehensive loss	(101)	(123)
Retained earnings	12,431	13,606
Total stockholders' equity	12,817	13,854
Total liabilities and stockholders' equity	$ 16,729	$ 18,426

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

	Three Months Ended March 31,	
	2024	2023
Operating activities		
Net (loss) income	$ (1,175)	$ 79
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Stock-based compensation	101	75
Depreciation and amortization	36	78
Amortization/accretion of investments	(27)	(17)
Loss on equity investments, net	13	18
Deferred income taxes	—	(310)
Other non-cash items	3	(4)
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable, net	755	272
Prepaid expenses and other assets	3	(212)
Inventory	(93)	216
Right-of-use assets, operating leases	16	4
Accounts payable	(303)	(117)
Accrued liabilities	(398)	(495)
Deferred revenue	(33)	(819)
Income taxes payable	(11)	18
Operating lease liabilities	(6)	4
Other liabilities	130	(15)
Net cash used in operating activities	(989)	(1,225)
Investing activities		
Purchases of marketable securities	(2,544)	(1,085)
Proceeds from maturities of marketable securities	1,573	1,360
Proceeds from sales of marketable securities	1,285	1,957
Purchases of property, plant and equipment	(196)	(113)
Acquisition of business, net of cash acquired	—	(85)
Investment in convertible notes and equity securities	—	(23)
Net cash provided by investing activities	118	2,011
Financing activities		
Proceeds from issuance of common stock through equity plans	15	9
Repurchase of common stock, including excise tax	—	(526)
Changes in financing lease liabilities	(1)	(25)
Net cash provided by (used in) financing activities	14	(542)
Net (decrease) increase in cash, cash equivalents and restricted cash	(857)	244
Cash, cash equivalents and restricted cash, beginning of year	2,928	3,217
Cash, cash equivalents and restricted cash, end of period	$ 2,071	$ 3,461

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, market dynamics, and its competitive profile; Moderna's 2024 financial framework and anticipated performance, including expected revenues; and anticipated milestones for Moderna's pipeline programs in 2024. 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, 2023, 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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