NEWS RELEASE

Moderna Reports Third Quarter 2023 Financial Results and Provides Business Updates

11/2/2023

- Third quarter 2023 revenues of $1.8 billion; Company expects 2023 revenues of at least $6 billion
- Spikevax U.S. market share to date increased to 45% from 36% in 2022
- Company anticipates 2024 revenue of approximately $4 billion and return to growth in 2025
- Company has significantly improved future cost of sales by resizing its manufacturing capacity, contributing to a third quarter net loss of $3.6 billion, primarily driven by mostly non-cash charges of $3.1 billion related to resizing and a tax valuation allowance
- Company's late-stage pipeline has six Phase 3 programs
- Company expects to break even in 2026 through product launches and disciplined investment

CAMBRIDGE, MA / ACCESSWIRE / November 2, 2023 / **Moderna, Inc.** (NASDAQ:MRNA) today reported financial results and provided business updates for the third quarter of 2023.

"Through this quarter, we demonstrated our ability to increase share in the U.S. market, and we now expect this year's vaccination rate to be similar to last fall," said Stéphane Bancel, Chief Executive Officer of Moderna. "In the third quarter, we significantly resized our manufacturing infrastructure to make our COVID-19 franchise profitable for 2024 and beyond. We are preparing to launch multiple products through 2025, including our RSV vaccine. We expect to return to sales growth in 2025 and, through disciplined investment, to break even in 2026."

Recent progress includes:

2023 Commercial Updates

COVID-19: The Company reported $1.8 billion in Spikevax® (COVID-19 vaccine) sales in the third quarter of 2023, which includes $0.9 billion of U.S. sales and $0.8 billion of international sales. This leads to $3.9 billion in vaccine sales for the year through the third quarter. The Company believes that the U.S. market for fall 2023 will be at least 50 million doses, supporting total 2023 Spikevax sales of at least $6 billion. The U.S. fall 2023 vaccinations administered in retail pharmacies to date are tracking similarly to the 2022 fall season, despite a later launch. Spikevax is available in all leading pharmacies and points of care and continues to gain market share. With 45% cumulative market share1 as of the most recently available date in October, Moderna's market share in the fall 2023 season is tracking ahead of its cumulative market share of 36% during the fall 2022 U.S. vaccination season.

The Company continues to focus on public health efforts to increase vaccination rates globally. In the United States, the Company has undertaken significant marketing and awareness campaigns, working closely with vaccinators and others to drive a robust vaccination season, including by activating the medical community, supporting and re-engaging customers (including those who deferred updated vaccination due to recent infections) and amplifying the voices of credible influencers.

RSV: The Company continues to expect the launch of its RSV vaccine in 2024 with a potential best-in-class profile. Moderna has submitted marketing authorization applications globally for mRNA-1345, a vaccine for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) and acute respiratory disease (ARD) in adults aged 60 years or older. The Company filed for a Biologics License Application (BLA) with the FDA and used a Priority Review Voucher (PRV) to accelerate review.

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. mRNA vaccine technology has a well-established safety and tolerability profile, with over 1 billion COVID-19 doses administered. 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. In addition to older adults, mRNA-1345 is being investigated in a fully enrolled, ongoing Phase 1 trial in pediatric populations.

Moderna is preparing for the marketing launch of mRNA-1345 and believes its U.S. COVID-19 market share to date demonstrates the Company's ability to compete in the commercial market. The Company is encouraged by early indications of strong consumer awareness and demand in the RSV market. Moderna believes that clinical data for its RSV vaccine supports a best-in-class profile and that its ready-to-use pre-filled syringes (PFS) offer another competitive differentiator over currently licensed products, which require multiple preparatory steps by pharmacists and clinicians. Feedback from clinicians and customers in the COVID-19 market, where Moderna has a

similar presentation, validates the benefits of PFS administration. The Company's pre-launch activities at this time are largely focused on scientific exchanges and public health engagements.

Third Quarter 2023 Financial Results

Revenue: Total revenue for the third quarter of 2023 was $1.8 billion, compared to $3.4 billion in the same period in 2022, mainly due to a decrease in sales of the Company's COVID-19 vaccine. Net product sales for the third quarter of 2023 were $1.8 billion, a decrease of 44% compared to the same period in 2022, primarily driven by lower sales volume and partially offset by a higher average selling price.

Cost of Sales: Cost of sales for the third quarter of 2023 was $2.2 billion. Moderna has made substantial progress during the quarter in resizing its COVID-19 manufacturing footprint to accelerate gross margin expansion toward its longer-term target of 75-80%. In addition to $0.4 billion in unit driven manufacturing, distribution cost and royalties, the remaining $1.9 billion includes the following charges: $1.3 billion for inventory write-downs related to excess and obsolete COVID-19 product, contract manufacturing wind-down cost of $0.5 billion, and cancellation fees of $0.1 billion. $1.4 billion of these charges were primarily driven by resizing efforts in the third quarter, with an additional $0.2 billion expected in the fourth quarter of 2023.

Research and Development Expenses: Research and development expenses for the third quarter of 2023 increased by 41% to $1.2 billion, in comparison to the same quarter of 2022. The growth in spending was mainly due to an increase in clinical trial-related expenses, largely driven by increased clinical development activities, particularly with respect to the Company's respiratory and oncology programs.

Selling, General and Administrative Expenses: Selling, general and administrative expenses for the third quarter of 2023 increased by 59% to $442 million, in comparison to the third quarter of 2022. The growth in spending was primarily due to increased personnel-related cost and outside services spend, driven by the build-out of our commercial activities and medical affairs in particular to support the launch of the U.S. commercial market.

Income Taxes: Income taxes for the third quarter of 2023 were $1.7 billion, which is primarily driven by a $1.7 billion non-cash charge related to a valuation allowance on deferred tax assets. This valuation allowance does not impact cash flows, future returns or the Company's ability to utilize deferred tax assets in future periods.

Net Income (Loss): Net loss was $3.6 billion for the third quarter of 2023, compared to net income of $1.0 billion for the third quarter of 2022, primarily driven by mostly non-cash charges of $3.1 billion related to resizing and tax allowances.

Earnings (Loss) Per Share: Diluted loss per share was $9.53 for the third quarter of 2023, compared to diluted

earnings per share of $2.53 for the third quarter of 2022.

Cash, Cash Equivalents and Investments: Cash, cash equivalents and investments were $12.8 billion as of September 30, 2023, down from $14.6 billion as of June 30, 2023, driven by the operating loss in the quarter.

2023 Financial Framework

Product Sales: The Company now expects product sales of at least $6 billion for 2023. The largest remaining variable to sales for the year relates to U.S. vaccination rates, and the estimate assumes trends consistent with the fall 2022 period.

Cost of Sales: The Company now expects cost of sales to be approximately $5 billion for the year, inclusive of charges of approximately $1.6 billion across the third and fourth quarters related to proactive resizing of the Company's manufacturing footprint. Before the resizing charges of $1.6 billion, costs of sales would be at the lower end of previous guidance range of $3.5 billion to $4 billion.

Respiratory Cost of Sales Framework: The Company's manufacturing resizing is expected to drive more predictable cost of sales going forward. Write-downs/charges are expected to be less than 10% of sales in 2024 and beyond (74% year to date). Moderna's resized footprint is now better positioned to scale with volume. At a $4 billion sales level, the Company expects cost of sales of approximately 35%, reducing to approximately 30% at $6 billion of sales and 20-25% at higher sales levels.

Research and Development (R&D) and Selling, General and Administrative (SG&A): The Company now expects full-year 2023 expenses of approximately $6.3 billion (previously $6 billion), with approximately $4.8 billion in R&D (previously $4.5 billion).

Income Taxes: The Company now anticipates a full-year tax expense of approximately $0.8 billion to $1.0 billion, driven by an increase in valuation allowance on deferred tax assets (previously a benefit of ~$0.7-1.0 billion). This valuation allowance does not impact cash flows, future returns or the Company's ability to utilize deferred tax assets in future periods.

Capital Expenditures: The Company expects capital expenditures for 2023 of approximately $0.9 billion (previously $1.0 billion).

Moderna Operating Principles

The Company expects its COVID-19 franchise to be profitable in its anticipated sales scenarios for 2024 and beyond. While Moderna plans to continue to invest in its business to drive an unparalleled opportunity for organic sales growth, the Company will be disciplined and will adjust its investments in R&D and SG&A based on its sales performance. Moderna expects to break even in 2026 through product launches and disciplined investments. The Company's current balance sheet is sufficient to fund its planned investments without raising additional equity.

Early Thoughts on 2024 and 2025 Sales

Moderna is projecting approximately $4 billion in sales in 2024, mostly in the second half of the year, primarily due to COVID-19 vaccine global sales and the launch of its RSV vaccine. In 2025, the Company expects to return to organic sales growth. The Company is projecting cost of sales as a percentage of sales to be approximately 35% in 2024, which is expected to improve with sales increasing in 2025. R&D expenses are expected to be approximately $4.5 billion in 2024 and flat to down in 2025. SG&A expenses are expected to be approximately $1.3 billion in 2024 and flat to down in 2025. Taxes are expected to be negligible in both 2024 and 2025. The Company expects capital expenditures to be approximately $0.9 billion in 2024 and materially lower in 2025, following the completion of manufacturing sites in Australia, Canada and the United Kingdom. Moderna expects to break even in 2026. The Company expects an ending cash balance of approximately $9 billion in 2024 and in the range of $6 billion to $7 billion in 2025.

Clinical Updates

Moderna's mRNA platform is positioned to continue to deliver significant impact with our mRNA medicines. The Company is anticipating up to 15 launches in the next five years and provided a comprehensive overview of its pipeline and clinical programs at **R&D Day** in September. Moderna currently has therapeutics in development across four therapeutic areas, with a total of 43 development programs. Other notable updates are provided below.

Respiratory : Moderna has advanced three respiratory disease programs to positive Phase 3 data (COVID-19, RSV, Influenza).

Moderna also recently announced positive interim results from the Phase 1/2 trial of mRNA-1083, an investigational

combination vaccine against seasonal influenza and COVID-19. Moderna's investigational combination vaccines are designed to deliver value to individuals, providers and healthcare systems through higher compliance, easier administration and greater convenience.

The ongoing Phase 1/2 clinical trial (**ClinicalTrials.gov** Identifier: NCT05827926) is a randomized, observer blind study evaluating the safety and immunogenicity of mRNA-1083 compared to a standard dose influenza vaccine, Fluarix, in adults 50-64 years of age and against an enhanced influenza vaccine, Fluzone HD, in adults 65-79 years of age. For both age groups, mRNA-1083 was compared against Spikevax booster.

The Company also recently announced that it has initiated a Phase 3 trial of mRNA-1083 in 2023 and is targeting initial regulatory approval for the combination vaccine in 2025. The Phase 3 study will evaluate the immunogenicity, safety, and reactogenicity of mRNA-1083 as compared with active control, co-administered licensed influenza and SAR-CoV-2 vaccines in 8,000 healthy adults 50 years of age or older.

mRNA-1083 has the potential to efficiently reduce the overall burden of acute viral respiratory diseases by providing simultaneous protection against influenza and SARS-CoV-2 viruses in a single injection. mRNA-1083 offers greater convenience and has the potential to lead to increased compliance with vaccine recommendations. This approach could benefit public health by synergistically increasing coverage rates against influenza and SARS-CoV-2 viruses.

Latent: The pivotal Phase 3 study of Moderna's CMV vaccine candidate (mRNA-1647), known as CMVictory, is fully enrolled including an adolescent cohort. The trial evaluates the efficacy, safety and immunogenicity of mRNA-1647 in the prevention of primary infection in women of childbearing age.

INT: In April 2023, Moderna and Merck reported the results from the Phase 2b KEYNOTE-942/mRNA-4157-P201 trial evaluating mRNA-4157 (V940), an investigational individualized neoantigen therapy (INT), in combination with KEYTRUDA, Merck's anti-PD-1 therapy, in patients with resected high-risk melanoma (stage III/IV). In the overall intention-to-treat population, adjuvant treatment with mRNA-4157 (V940) in combination with KEYTRUDA demonstrated a statistically significant and clinically meaningful improvement in recurrence-free survival (RFS) and reduced the risk of recurrence or death by 44% (HR=0.56 [95% CI, 0.309-1.017]; one-sided p value=0.0266) compared with KEYTRUDA alone. In June, the Company announced a statistically significant and clinically meaningful improvement in distant metastasis-free survival from the Phase 2b KEYNOTE-942/mRNA-4157-P201 trial. mRNA-4157-P201/KEYNOTE-942 is the first randomized trial to demonstrate improvement in recurrence-free survival and distant metastasis-free survival with an individualized neoantigen therapy approach. The Company expects to provide additional data from the Phase 2 study in the fourth quarter of 2023.

Merck and Moderna announced the initiation of a pivotal Phase 3 study (V940-001) to evaluate the safety and

efficacy of mRNA-4157 (V940) in combination with KEYTRUDA in people with resected high-risk (Stage IIB-IV) melanoma compared to KEYTRUDA alone. The primary endpoint of the study is recurrence-free survival, and secondary endpoints include distant metastasis-free survival, overall survival and safety. That trial is underway globally.

The Companies will also imminently commence a Phase 3 trial in non-small cell lung cancer (NSCLC) in patients with resected stage II-IIIB NSCLC who have received adjuvant chemotherapy, with no recurrence. The primary endpoint is disease free survival compared to pembrolizumab. Secondary endpoints are overall survival, distant metastasis-free survival, and safety. The trial is expected to enroll approximately 868 patients.

Moderna and Merck plan to expand the INT development program to additional tumor types.

Moderna is scaling manufacturing to support clinical development and commercial markets. The Company is also currently building a manufacturing site in Marlborough, MA as a commercial INT manufacturing facility.

Corporate Updates

- Moderna **announced** strategic partnerships with Immatics and CARsgen
- Moderna **announced** positive clinical results across cancer, rare disease and infectious disease at its 8th annual R&D Day

Company Accolades:

- Moderna was ranked as one of the top employers in the global biopharmaceutical industry by Science and Science Careers' 2023 Top Employers Survey (ninth consecutive year on the list)
- Moderna was named to the Boston Business Journal's annual list of the **Most Charitable Companies in Massachusetts** (first year on the list)
- Moderna was **recognized** as a top-scoring company on the Disability: IN's Disability Equality Index (second consecutive year on the list)

Key 2023 Investor and Analyst Event Dates

- Digital Day: November 8
- ESG Day: December 7

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on November 2, 2023. 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/BI9ee4891809624391a5618bb9e2ca440f**
- 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

In over 10 years since its inception, Moderna has transformed from a research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio and integrated manufacturing facilities that allow for rapid clinical and commercial production at scale. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use and approval of one of the earliest and most effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past nine years. To learn more, visit **www.modernatx.com.**

MODERNA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in millions, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Net product sales	$ 1,757	$ 3,120	$ 3,878	$ 13,576
Other revenue1	74	244	159	603
Total revenue	1,831	3,364	4,037	14,179
Operating expenses:				
Cost of sales	2,241	1,100	3,764	3,498
Research and development	1,160	820	3,439	2,084
Selling, general and administrative	442	278	1,079	757

Total operating expenses	3,843	2,198	8,282	6,339
(Loss) income from operations	(2,012)	1,166	(4,245)	7,840
Interest income	105	58	318	113
Other expense, net	(51)	(7)	(85)	(33)
(Loss) income before income taxes	(1,958)	1,217	(4,012v	7,920
Provision for income taxes	1,672	174	919	1,023
Net (loss) income	$ (3,630)	$ 1,043	$ (4,931)	$ 6,897
(Loss) earnings per share:				
Basic	$ (9.53)	$ 2.67	$ (12.89)	$ 17.41
Diluted	$ (9.53)	$ 2.53	$ (12.89)	$ 16.46
Weighted average common shares used in calculation of (loss) earnings per share:				
Basic	381	390	382	396
Diluted	381	412	382	419

1 Includes grant revenue and collaboration revenue

MODERNA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in millions)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,932	$ 3,205
Investments	4,641	6,697
Accounts receivable, net	1,866	1,385
Inventory	487	949
Prepaid expenses and other current assets	873	1,195
Total current assets	10,799	13,431
Investments, non-current	5,273	8,318
Property, plant and equipment, net	1,952	2,018
Right-of-use assets, operating leases	765	121
Deferred tax assets	-	982
Other non-current assets	661	988
Total assets	$ 19,450	$ 25,858
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 494	$ 487
Accrued liabilities	2,224	2,101

Deferred revenue	1,372	2,038
Income taxes payable	56	48
Other current liabilities	239	249
Total current liabilities	4,385	4,923
Deferred revenue, non-current	166	673
Operating lease liabilities, non-current	697	92
Financing lease liabilities, non-current	575	912
Other non-current liabilities	172	135
Total liabilities	5,995	6,735
Stockholders' equity:		
Additional paid-in capital	277	1,173
Accumulated other comprehensive loss	(211)	(370)
Retained earnings	13,389	18,320
Total stockholders' equity	13,455	19,123
Total liabilities and stockholders' equity	$ 19,450	$ 25,858

MODERNA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in millions)

	Nine Months Ended September 30,	
	2023	2022
Operating activities		
Net (loss) income	$ (4,931)	$ 6,897
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Stock-based compensation	226	164
Depreciation and amortization	419	268
Amortization/accretion of investments	(41)	35
Loss on equity investments, net	16	-
Deferred income taxes	934	(473)
Other non-cash items	25	36
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable, net	(481)	480
Prepaid expenses and other assets		

Inventory	772	(669)
Right-of-use assets, operating leases	462	(636)
Accounts payable	(657)	29
Accrued liabilities	(8)	89
Deferred revenue	63	354
Income taxes payable	(1,173)	(2,691)
Operating lease liabilities	8	(810)
Other liabilities	605	(27)
Net cash (used in) provided by operating activities	21	273
	(3,740)	3,319
Investing activities		
Purchases of marketable securities	(2,097)	(8,925)
Proceeds from maturities of marketable securities	4,711	2,222
Proceeds from sales of marketable securities	2,725	2,918
Purchases of property, plant and equipment	(487)	(308)
Acquisition of business, net of cash acquired	(85)	-
Investment in convertible notes and equity securities	(23)	(35)
Net cash provided by (used in) investing activities	4,744	(4,128)
Financing activities		
Proceeds from issuance of common stock through equity plans	31	40
Repurchase of common stock, including excise tax	(1,153)	(2,927)
Changes in financing lease liabilities	(146)	(123)
Net cash used in financing activities	(1,268)	(3,010)
Net decrease in cash, cash equivalents and restricted cash	(264)	(3,819)
Cash, cash equivalents and restricted cash, beginning of year	3,217	6,860
Cash, cash equivalents and restricted cash, end of period	$ 2,953	$ 3,041

SpikeVax® is a registered trademark of Moderna.

Fluzone® is a registered trademark of Sanofi Pasteur.

Fluarix® is a registered trademark of the GlaxoSmithKline group of companies.

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 expected revenues in 2023 and 2024;

Moderna's ability to launch multiple products in 2024 and 2025 and return to sales growth in 2025; Moderna's future cost of sales; Moderna's expectation to break even in 2026; the sufficiency of Moderna's current cash balances to fund future plans, and Moderna's plans not to raise additional equity; the 2023 U.S. vaccination rate; Spikevax's market share and the ability to continue to gain market share; Moderna's ability to compete in the broader respiratory vaccine commercial market; the anticipated profitability of Moderna's COVID-19 franchise for 2024 and beyond; Moderna's anticipated launches of its RSV vaccine in 2024 with a potential best-in-class profile and its COVID + flu combination vaccine in 2025; Moderna's 2023 through 2025 financial framework; the potential for Moderna to launch up to 15 products in the next five years; the anticipated benefits of combination vaccines; the anticipated initial regulatory approval for mRNA-1083 in 2025; the expectation that Moderna will provide additional data from its Phase 2 INT study in the fourth quarter of 2023; Moderna's and Merck's Phase 3 study of mRNA-4157 in melanoma patients and expected commencement of a Phase 3 trial in NSCLC patients; and Moderna's and Merck's plans to expand the INT development program to additional tumor types. 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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1 Based on information licensed from IQVIA: IQVIA RAPID Weekly Audit for September/October 2023, reflecting estimates of real-world activity.

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