NEWS RELEASE

Moderna Reports First Quarter 2023 Financial Results and Provides Business Updates

5/4/2023

- First quarter 2023 revenues of $1.9 billion; GAAP net income of $79 million and GAAP diluted EPS of $0.19
- Company in negotiations for new orders for fall of 2023 in U.S., Japan, and EU, in addition to reiterating 2023 minimum sales expectations of approximately $5.0 billion from previously announced COVID-19 vaccine Advanced Purchase Agreements
- Company preparing for potential 2024 commercial launch of its investigational RSV vaccine for older adults
- Company to begin Phase 3 trial this year of mRNA-4157, Moderna's individualized neoantigen therapy (INT) in combination with Keytruda®, for melanoma
- Company preparing for six major vaccine launches from respiratory franchise (COVID-19, RSV, Flu, and combinations), with expected annual sales of $8-15 billion by 2027

CAMBRIDGE, MA / ACCESSWIRE / May 4, 2023 / **Moderna, Inc**. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today reported financial results and provided business updates for the first quarter of 2023.

"We had a strong first quarter, with $1.9 billion in revenue, clearly indicating that we are on our way to deliver on the $5 billion of signed Advance Purchase Agreements for 2023. In addition, we are encouraged by the progress of new COVID-19 vaccine contracts in the U.S. for this fall with pharmacy chains, hospital networks and multiple U.S. government agencies. Similar discussions are ongoing with Japan, the EU, and other key markets such as Australia, which recently ordered additional COVID-19 vaccines," said Stéphane Bancel, Chief Executive Officer of Moderna. "At AACR, we presented detailed results for the treatment of melanoma with our individualized neoantigen therapy in combination with Keytruda, showing a 44% reduction of recurrence or risk of death in melanoma compared to

Keytruda alone. These data could represent a profound change in the treatment of melanoma, and we are quickly beginning Phase 3 trials in melanoma as well as lung cancer. We also are pleased with our progress in rare disease, where we have now advanced to the dose-expansion phase of our investigational mRNA therapy for propionic acidemia, and have upcoming interim data being shared at ASGCT this month. At the same time, we are fully preparing for potential commercial launches of two products in 2024, our RSV and flu vaccines."

Recent progress includes:

Respiratory Vaccines
Moderna's respiratory pipeline includes Phase 3 trials against RSV, influenza, and a next-generation COVID-19 candidate. The pipeline includes four additional influenza vaccines with expanded antigens, vaccines against other respiratory pathogens (e.g., hMPV), and six combination vaccine programs.

Commercial and Phase 3 trials

COVID-19
According to current FDA guidance for COVID-19 vaccination, individuals who are 65 years of age or older and those who are immunocompromised are now eligible to receive an additional dose. New COVID-19 vaccination recommendations are expected from the FDA following the upcoming June strain-selection meeting.

Moderna's next-generation, refrigerator-stable COVID-19 vaccine, mRNA-1283, has demonstrated encouraging results in multiple clinical studies and recently began dosing participants in a Phase 3 trial.

RSV
Moderna's RSV vaccine candidate, mRNA-1345, met its primary efficacy endpoint in older adults, and topline data were released in the first quarter. Additional updates were presented at recent medical conferences (RSVVW and ECCMID), demonstrating consistently high efficacy across the clinical spectrum of RSV disease in adults aged 60 years and up. No cases of Guillain-Barré syndrome (GBS) or other demyelinating events have been reported among mRNA-1345 trial participants to date. Based on these results, Moderna expects to submit for regulatory approval.

Flu
The Company's first influenza vaccine candidate, mRNA-1010, is currently being evaluated in Phase 3 trials. A Phase 3 trial (P301) was conducted in the Southern Hemisphere to evaluate safety and non-inferior immunogenicity compared to a licensed flu vaccine; interim results from that study were previously **announced** in February. An additional Phase 3 trial (P302) is being conducted in the Northern Hemisphere to evaluate safety and non-inferior efficacy compared to a licensed flu vaccine. The independent DSMB has completed the first interim analysis of efficacy and **informed** the company that mRNA-1010 did not meet the statistical threshold necessary to declare

early success and recommended that the trial continues with efficacy follow-up towards the next analysis. The DSMB did not identify any safety concerns.

A preliminary analysis of immunogenicity from a subset of participants in the P302 trial has also been completed. In this analysis, mRNA-1010 demonstrated geometric mean titer ratios consistent with superiority against both influenza A strains (A/H1N1, A/H3N2) and consistent with non-inferiority against both influenza B strains (B/Victoria, B/Yamagata) relative to the licensed comparator. The P302 study will continue until the end of the current flu season.

The Company has also initiated a Phase 3 immunogenicity trial (P303) to test an updated formulation of mRNA-1010 that is expected to lead to improved immune responses against influenza B strains and is intended to enable licensure of mRNA-1010 through accelerated approval.

Combination Respiratory Vaccines

The Phase 1/2 trial of mRNA-1083, targeting COVID-19 + flu, using the Company's next-generation COVID-19 vaccine candidate, mRNA-1283, and seasonal flu vaccine candidate mRNA-1010, has initiated enrollment.

Latent Virus Vaccines

Phase 3 trial

The pivotal Phase 3 study of Moderna's CMV vaccine candidate (mRNA-1647), known as CMVictory, is ongoing, with enrollment more than 50% complete. The adolescent trial for mRNA-1647 has dosed its first participants.

Therapeutics

The Company's therapeutics portfolio spans immuno-oncology, rare diseases, autoimmune diseases, and cardiovascular diseases.

Immuno-oncology

Moderna and Merck's recent **announcement** and presentation at the American Association for Cancer Research (AACR) on April 16, 2023, demonstrated that the Phase 2b KEYNOTE-942/mRNA-4157-P201 trial of mRNA-4157/V940, an investigational individualized neoantigen therapy, in combination with pembrolizumab met the primary efficacy endpoint of improving recurrence-free survival (RFS) versus standard of care pembrolizumab for the adjuvant treatment of patients with stage III/IV melanoma following complete resection. Adjuvant treatment with mRNA-4157/V940 in combination with pembrolizumab reduced the risk of recurrence or death by 44% (HR=0.56 [95% CI, 0.31-1.08]; one-sided p-value=0.0266) compared with pembrolizumab alone. The 12-month RFS rate was 83.4% (95% CI, 74.7-89.3) and 77.1% (95% CI, 62.5-86.6) in the combination and control arms, respectively. The 18-month RFS rate was 78.6% (95% CI, 69.0-85.6) and 62.2% (95% CI, 46.9-74.3) in the combination and control arms, respectively.

A second AACR presentation reviewed data from a subgroup analysis to assess RFS in biomarker-high and -low subgroups across study arms. Irrespective of tumor mutational burden (TMB) status, the results indicate that targeting an individual patient's unique tumor mutations with mRNA-4157/V940 demonstrates improved RFS when administered in combination with pembrolizumab compared to pembrolizumab monotherapy. The association between TMB and mRNA-4157/V940 treatment effect will be further explored in upcoming planned studies.

Moderna and Merck plan to discuss results with regulatory authorities, initiate a Phase 3 study in melanoma in 2023, and rapidly expand to additional tumor types, including non-small cell lung cancer (NSCLC).

Rare diseases: Propionic Acidemia

The Phase 1/2 open-label, dose optimization trial of mRNA-3927, an mRNA therapeutic candidate for propionic acidemia (PA), has advanced to the dose-expansion phase to further evaluate safety and efficacy, and confirm the recommended dose for future clinical studies. This trial includes a dose optimization stage (cohorts 1-5), followed by a dose expansion stage with progression dependent on the safety of the preceding cohort. A total of 257 doses have been administered with no dose-limiting toxicities or study discontinuations due to drug-related treatment-emergent adverse events. Five of the 15 study participants have been dosed with over one year of continuous treatment. All eligible participants have elected to continue with treatment by participating in the Open-Label Extension Study. Interim data will be presented at the American Society of Gene & Cell Therapy (ASGCT) on May 18, 2023.

Moderna now has 47 programs1 in development across 45 development candidates, of which 36 are currently in active clinical trials. The Company's updated pipeline can be found at **www.modernatx.com/pipeline**. Moderna and collaborators have published more than 140 peer-reviewed publications.

First Quarter 2023 Financial Results

Revenue: Total revenue for the first quarter of 2023 was $1.9 billion, compared to $6.1 billion in the same period in 2022, mainly due to a decrease in sales of the Company's COVID-19 vaccines. Product sales for the first quarter of 2023 were $1.8 billion, a decrease of 69%, compared to the same period in 2022, primarily driven by lower sales volume.

Cost of Sales: Cost of sales for the first quarter of 2023 was $792 million. In addition to unit driven manufacturing costs, this includes royalties of $86 million and the following charges: $148 million for inventory write-downs related to excess and obsolete COVID-19 products, unutilized manufacturing capacity of $135 million, and losses on firm purchase commitments and related cancellation fees of $95 million. These charges, other than royalties, were driven by costs associated with surplus production capacity and an overall lower demand forecast, primarily for

lower income countries. Cost of sales as a percent of product sales was 43% of product sales, compared to 17% in the first quarter of 2022. The increase was driven by the aforementioned charges over lower product sales compared to the prior year, and higher manufacturing cost as the Company switched to smaller dose vials compared to the prior year, as well as lower product sales to absorb fixed manufacturing costs.

Research and Development Expenses: Research and development expenses for the first quarter of 2023 increased by 104% to $1.1 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 RSV, seasonal flu and CMV programs. The growth was also driven by an increase in personnel-related costs, due to increased headcount to support research and development efforts, and the Company's recently announced collaboration agreements with Life Edit and Generation Bio.

Selling, General and Administrative Expenses: Selling, general and administrative expenses for the first quarter of 2023 increased by 14% to $305 million, in comparison to the first quarter of 2022. The growth in spending was primarily due to increases in outside services spend and personnel-related costs, driven by commercial activities in support of the Company's marketed products and expansion.

Income Taxes: Income tax benefit for the first quarter of 2023 was $384 million, driven by the Company's full year outlook, which includes research and development credits, international provisions, and non-recurring items.

Net Income: Net income was $79 million in the first quarter of 2023, compared to net income of $3.7 billion for the first quarter of 2022.

Earnings Per Share: Diluted earnings per share was $0.19 in the first quarter of 2023, compared to diluted earnings per share of $8.58 for the first quarter of 2022.

2023 Commercial Updates

COVID-19: COVID-19 vaccine sales to Europe were $0.6 billion and sales to the rest of the world were $1.3 billion in the first quarter. The total of $1.8 billion in sales represents the vast majority of the projected $2 billion in sales from 2022 deferrals expected in the first half of 2023.2 The Company reiterates its expectation of 2023 minimum sales of approximately $5.0 billion from previously announced COVID-19 vaccine Advanced Purchase Agreements. The Company estimates the U.S. annual COVID-19 market to be 100 million doses. The Company is in active supply discussions for new orders for fall of 2023 in the U.S., Japan, and the EU In the U.S., this could include:

- Contracting with national/regional pharmacies, healthcare systems, government health providers (Veteran's Affairs, Centers for Disease Control and Prevention, Department of Defense, etc.), occupational health

providers, employers, physicians
- Contracting with Group Purchasing Organizations (GPOs) and Physician Buying Groups (PBGs)
- Establishing a national distribution infrastructure via Moderna Direct ecommerce site and distribution agreements with national wholesalers & distributors
- Utilizing a global supply chain to provide our COVID-19 vaccine in single-dose vials and pre-filled syringes in time to meet vaccination needs this fall

In further support of its COVID-19 vaccine commercial launch, the Company is establishing fall campaigns to support vaccinations alongside annual flu campaigns, partnering with the customer base to assist with identifying patients and simplify the vaccination experience, and utilizing an omni-channel approach to reach healthcare providers.

Respiratory Franchise: As previously **announced** at Vaccines Day, the Company is preparing for six potential major vaccine launches with expected annual sales of $8-15 billion by 2027 from the respiratory franchise (COVID-19, RSV, Flu and combinations).

RSV: The Company continues to expect a 2024 launch of its RSV vaccine and is undertaking a number of activities to raise awareness of the health and economic burden of RSV, including by presenting detailed data of its Phase 3 study at major medical meetings (RSVVW/ECCMID), with future presentations planned. The Company continues to be encouraged by payer, NITAG and key opinion leader feedback and has begun manufacturing the mRNA for its RSV vaccine in pre-filled syringes.

INT: The Company is identifying eligible cancer patient populations to potentially benefit from its individualized neoantigen therapy.

2023 Financial Framework

Advance Purchase Agreements (APAs): The Company has COVID-19 vaccine sales of approximately $5 billion currently contracted for 2023 delivery. The Company is in negotiations for additional COVID-19 vaccine orders in key markets, including the U.S., Japan, and the EU. Australia also recently ordered additional COVID-19 vaccines. The Company continues to expect total product sales in the first half of 2023 of approximately $2.0 billion (second quarter 2023 sales are expected to be between $0.2-$0.3 billion).

Cost of Sales: The company continues to expect cost of sales for the full year in the range of approximately 35-40% of product sales. For the second quarter 2023, the Company expects cost of sales between $0.5-$0.6 billion.

Research & Development (R&D) and Selling, General & Administrative (SG&A) Expenses: The Company continues to expect full-year 2023 expenses of approximately $6.0 billion, with approximately $4.5 billion in R&D.

Income Taxes: The Company now anticipates a full year tax benefit of $0.3-$0.5 billion, driven by R&D credits, international provisions, and nonrecurring items.

Capital Expenditures: The Company continues to expect to make capital investments for 2023 of approximately $1.0 billion.

Corporate Updates
Continued Growth:

- Moderna had approximately 4,350 employees as of March 31, 2023, compared to approximately 3,200 employees as of March 31, 2022.
- Moderna also **announced** plans to open new offices in Seattle, WA to provide technology solutions across the enterprise, and in South San Francisco, CA to focus on additional research and development within Moderna Genomics.

Corporate Development:

- Moderna and Generation Bio **announced** a strategic collaboration to develop non-viral genetic medicines
- Moderna and Life Edit Therapeutics **announced** a strategic collaboration to accelerate the development of novel in vivo gene editing therapies
- Moderna and CytomX **announced** a strategic research collaboration for mRNA-based conditionally activated therapeutics
- Moderna completed its acquisition of **OriCiro Genomics** in the first quarter 2023

Company Accolades : Moderna has been recognized as a **Great Place to Work** in the U.S. by Great Place To Work®

Key 2023 Investor and Analyst Event Dates

- R&D Day: September 13
- 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 May 4, 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/BI58bd807860ad4c289a8ce03ab024b978**

- 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. Moderna's capabilities came together to allow the authorized use and approval of one of the earliest and most effective vaccines against the COVID 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 eight 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 March 31,	
	2023	2022
Revenue:		
Product sales	$ 1,828	$ 5,925
Other revenue1	34	141
Total revenue	1,862	6,066
Operating expenses:		
Cost of sales	792	1,017
Research and development	1,131	554
Selling, general and administrative	305	268
Total operating expenses	2,228	1,839
(Loss) income from operations	(366)	4,227
Interest income	109	15

Other expense, net	(48)	(13)
(Loss) income before income taxes	(305)	4,229
(Benefit from) provision for income taxes	(384)	572
Net income	$ 79	$ 3,657
Earnings per share:		
Basic	$ 0.20	$ 9.09
Diluted	$ 0.19	$ 8.58
Weighted average common shares used in calculation of earnings per share:		
Basic	386	402
Diluted	405	426

1 Includes grant revenue and collaboration revenue

MODERNA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in millions, except per share data)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 3,441	$ 3,205
Investments	5,482	6,697
Accounts receivable	1,113	1,385
Inventory	732	949
Prepaid expenses and other current assets	1,354	1,195
Total current assets	12,122	13,431
Investments, non-current	7,442	8,318
Property, plant and equipment, net	2,018	2,018
Right-of-use assets, operating leases	117	121
Deferred tax assets	1,262	982
Other non-current assets	1,164	988
Total assets	$ 24,125	$ 25,858

Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 389	$ 487
Accrued liabilities	1,613	2,101
Deferred revenue	1,219	2,038
Income taxes payable	66	48
Other current liabilities	212	249
Total current liabilities	3,499	4,923
Deferred revenue, non-current	673	673
Operating lease liabilities, non-current	96	92
Financing lease liabilities, non-current	831	912
Other non-current liabilities	163	135
Total liabilities	5,262	6,735
Stockholders' equity:		
Additional paid-in capital	731	1,173
Accumulated other comprehensive loss	(267)	(370)
Retained earnings	18,399	18,320
Total stockholders' equity	18,863	19,123
Total liabilities and stockholders' equity	$ 24,125	$ 25,858

MODERNA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in millions)

	Years Ended December 31,	
	2023	2022
Operating activities		
Net income	$ 79	$ 3,657
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Stock-based compensation	75	44
Depreciation and amortization	78	79
Amortization/accretion of investments	(17)	18
Loss on equity investments, net	18	-
Deferred income taxes	(310)	(146)
Other non-cash items	(4)	-
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable	272	1

Prepaid expenses and other assets	(212)	(414)
Inventory	216	(501)
Right-of-use assets, operating leases	4	10
Accounts payable	(117)	(35)
Accrued liabilities	(495)	114
Deferred revenue	(819)	(805)
Income taxes payable	18	716
Operating lease liabilities	4	(10)
Other liabilities	(15)	35
Net cash (used in) provided by operating activities	(1,225)	2,763
Investing activities		
Purchases of marketable securities	(1,085)	(5,572)
Proceeds from maturities of marketable securities	1,360	441
Proceeds from sales of marketable securities	1,957	1,377
Purchases of property, plant and equipment	(113)	(132)
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	2,011	(3,921)
Financing activities		
Proceeds from issuance of common stock through equity plans	9	12
Repurchase of common stock	(526)	(623)
Changes in financing lease liabilities	(25)	(31)
Net cash used in financing activities	(542)	(642)
Net increase (decrease) in cash, cash equivalents and restricted cash	244	(1,800)
Cash, cash equivalents and restricted cash, beginning of year	3,217	6,860
Cash, cash equivalents and restricted cash, end of period	$ 3,461	$ 5,060

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: anticipated sales, including the timing of sales, under advance purchase agreements for delivery in 2023 and the associated dollar amounts to be received, which should not be construed as expected 2023 revenue; COVID market dynamics and potential additional sales in key markets; Moderna's plans to file for regulatory approval for mRNA-1345 (RSV for older adults) and plans to launch commercial sales in 2024; the safety and tolerability profile for mRNA-1345; plans to launch commercial sales of Moderna's seasonal flu vaccine in 2024; the timing for launches of respiratory vaccines and the potential future revenues associated with such sales; the potential for the P303 Phase 3 trial of mRNA-1010 to demonstrate results that could lead to accelerated approval for the seasonal flu vaccine candidate; Moderna's collaboration with Merck to jointly develop and commercialize mRNA-4157/V940; the ability of mRNA-4157/V490 to improve recurrence free survival rates in melanoma patients and other cancer patients; plans to initiate a Phase 3 in adjuvant melanoma in 2023 for mRNA-4157/V940 and plans to expand into additional cancer types, including lung cancer; timing for the

commercial launch of RSV and seasonal flu; plans for dose selection and study expansion for Moderna's propionic acidemia therapeutic; and Moderna's 2023 financial framework, including potential additional COVID-19 vaccine sales, cost of goods sold, spending on research and development, and anticipated tax benefit for the full year. 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 Includes separate COVID Vaccine (mRNA-1273) programs in development for adults, pediatrics & adolescents and separate RSV vaccine (mRNA-1345) programs in development for adults and pediatrics.

2 Note that figures may not sum due to rounding

SOURCE: Moderna, Inc.

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