Moderna Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Provides Business Updates

Fourth quarter 2022 revenues of $5.1 billion; GAAP net income of $1.5 billion and GAAP diluted EPS of $3.61

Full-year 2022 revenues of $19.3 billion; GAAP net income of $8.4 billion and GAAP diluted EPS of $20.12

Company reiterating approximately $5 billion in COVID-19 sales contracted for delivery in 2023 and expecting additional sales from key markets

Company will file for regulatory approval for mRNA-1345, Moderna's investigational RSV vaccine for older adults, in the first half of 2023. mRNA-1345 was recently granted FDA Breakthrough Therapy Designation

mRNA-1010 Phase 3 flu vaccine interim efficacy analysis expected to be reviewed by an independent DSMB before the end of the first quarter

mRNA-4157, Moderna's investigational personalized cancer vaccine in combination with Keytruda®, was granted Breakthrough Therapy Designation; full data set to be shared at upcoming medical oncology meeting and in peer reviewed publication

Company R&D investments planned to increase to $4.5 billion in 2023

CAMBRIDGE, Mass.—(ACCESS WIRE)—February 23, 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 fourth quarter and fiscal year 2022.

"2022 was another impressive year for Moderna, with over $19 billion in revenue and significant clinical breakthroughs across our portfolio. We continue to provide our Omicron-targeting bivalent vaccines worldwide, with the latest real-world evidence highlighting the continued protection of our vaccines against hospitalization and death," said Stéphane Bancel, Chief Executive Officer of Moderna. "Our infectious disease platform continues to progress with positive Phase 3 data in RSV for older adults. We are investing to scale Phase 3 manufacturing for personalized cancer vaccines so that we can run several Phase 3 studies simultaneously. With planned R&D investments of $4.5 billion for the year, I am excited about the new medicines we believe we will bring to patients in the coming few years."

Moderna is also announcing that Juan Andres, currently President, Strategic Partnerships and Enterprise Expansion, will be retiring from the Company in May after more than six years.

"Juan has played a tremendous role since joining Moderna in 2017. Juan served as Chief Technical Operations and Quality Officer and led our manufacturing from an early-stage clinical development company to a commercial company. In 2020 and 2021, Juan did a historic job with his team to scale Moderna for a global commercial launch, during a pandemic. It is unbelievable that he led the team from having made less than 100,000 doses across our entire portfolio in 2019 to more than 800 million doses in 2021 of our COVID-19 vaccine globally, all during a pandemic," said Mr. Bancel. "Very few manufacturing leaders could have led such an achievement during such a challenging time. We, and the

hundreds of millions of people across the globe who received the Moderna COVID-19 vaccine, owe Juan our gratitude."

Recent Progress Includes:

Respiratory Vaccines

Approved and Phase 3 trials

- Spikevax Bivalent BA.4/BA.5 authorized under EUA in the U.S. as a booster dose for all age groups from 5 months.
- RSV vaccine in older adults (**mRNA-1345**) met its primary efficacy endpoint and received Breakthrough Therapy Designation from FDA. mRNA-1345 demonstrated vaccine efficacy of 83.7% against RSV lower respiratory tract disease, defined by 2 or more symptoms, and 82.4% with 3 or more symptoms in older adults. mRNA-1345 was generally well-tolerated, with no safety concerns identified by the Data Safety Monitoring Board (DSMB). Based on these results, Moderna expects to submit a Biologics License Application (BLA) for mRNA-1345 to the FDA in the first half of 2023. The pediatric Phase 1 trial of mRNA-1345 is fully enrolled.
- Flu (**mRNA-1010**) interim analysis from Phase 3 immunogenicity and safety trial demonstrated mRNA-1010 achieved superiority on seroconversion rates for A/H3N2 and A/H1N1, superiority on geometric mean titer ratios for A/H3N2, and non-inferiority on geometric mean titer ratios for A/H1N1. Non-inferiority was not met for seroconversion rates, and geometric mean titer ratios for the influenza B/Victoria- and B/Yamagata-lineage strains. mRNA-1010 was found to be generally well-tolerated.
- The ongoing mRNA-1010 Phase 3 efficacy study (P302) conducted in the Northern Hemisphere has accrued more than 200 PCR-confirmed cases. The first per-protocol interim analysis of efficacy is expected to be reviewed by an independent DSMB before the end of the first quarter.

Latent Vaccines

Phase 3 trials

- CMV vaccine **(mRNA-1647)** pivotal Phase 3 study, known as CMVictory, is ongoing, with enrollment more than 40% complete. CMV vaccine candidate **mRNA-1647** adolescent trial dosed its first participants.

Early clinical

- First participants, adults 50 years of age or older, dosed in Phase 1/2 trial of varicella-zoster virus (VZV) candidate **mRNA-1468**. VZV causes chickenpox, commonly affecting children and young adults, and shingles in adults.

Therapeutics

Immuno-oncology

- Personalized cancer vaccine (PCV) Phase 2 evaluating **mRNA-4157/V940** in combination with KEYTRUDA®, Merck's anti-PD-1 therapy, as adjuvant treatment for patients with high-risk melanoma reported positive topline data, showing a 44% reduction of recurrence or death versus Keytruda alone.
- The companies have received Breakthrough Therapy Designation for mRNA-4157/V940.
- As previously announced on October 12, Merck exercised its option to jointly develop and commercialize mRNA-4157/V940 pursuant to the terms of its existing Collaboration and License Agreement, and Moderna received $250 million from Merck in the fourth quarter in connection

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

Rare diseases

- The Phase 1/2 Paramount study of propionic acidemia (PA) candidate **(mRNA-3927)** is enrolling patients in cohort 5 (0.9mg/kg). Encouraging clinical benefit has been observed to date and all eligible participants continue to opt-in to the Open Label Expansion. Next step is dose selection for the expansion arm of the Phase 1/2 study.
- Moderna's partner, Vertex, initiated Phase 1 trial for **VX-522**, an mRNA therapy targeted at treating the underlying cause of cystic fibrosis (CF) lung disease for those who cannot benefit from a cystic fibrosis transmembrane conductance regulator (CFTR) modulator. VX-522 is Moderna's first inhaled mRNA to enter the clinic.

Cardiovascular disease

- Phase 1B trial of heart failure treatment candidate, **mRNA-0184** was initiated. mRNA-0184 is designed to produce the naturally occurring cardioprotective hormone relaxin.

Moderna now has 48 programs[1] in development across 45 development candidates, of which 38 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.

Fourth Quarter and Full Year 2022 Financial Results

Revenue: Total revenue for the fourth quarter of 2022 was $5.1 billion, compared to $7.2 billion in the same period in 2021, mainly due to a decrease in sales of the Company's COVID-19 vaccines. Product sales for the fourth quarter of 2022 were $4.9 billion, a decrease of 30% compared to the same period in 2021, primarily driven by lower sales volume, compared to overall higher demand in the prior year and the related manufacturing ramp up in the fourth quarter of 2021.

Cost of Sales: Cost of sales was $1.9 billion, or 39% of product sales, for the fourth quarter of 2022, including third-party royalties of $604 million, of which $400 million related to a catch-up payment to the National Institute of Allergy and Infectious Diseases (NIAID) for a new royalty-bearing license agreement executed in December. The agreement provides for low single-digit royalties on future COVID-19 vaccine sales. Cost of sales, as a percentage of product sales, increased by 25 percentage points, from 14% in the same period in 2021. The increase was driven by increased royalties, a charge of $297 million for inventory write-downs related to COVID-19 products that have exceeded or are expected to exceed their approved shelf-lives prior to being used, a loss on firm purchase commitments and related cancellation charges of $281 million, and an expense for unutilized manufacturing capacity and related contract manufacturing organization charges of $376 million. These charges, other than royalties, are driven by costs associated with surplus production capacity, overall lower demand and a

[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.

shift to our most recent Omicron-targeting COVID-19 bivalent booster, mRNA-1273.222

Research and Development Expenses: Research and development expenses for the fourth quarter of 2022 increased by 87% to $1.2 billion, in comparison to the same quarter of 2021. 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 our RSV, seasonal flu and CMV programs. The growth was also driven by the acquisition of a Priority Review Voucher and an increase in personnel-related costs due to increased headcount to support our increased research and development efforts.

Selling, General and Administrative Expenses: Selling, general and administrative expenses for the fourth quarter of 2022 increased by 87% to $375 million, in comparison to the same quarter of 2021. The growth in spending was primarily due to increased external and marketing spend, driven by commercial activities in support of the Company's marketed products and build-out.

Effective Tax Rate: The effective tax rate was 11% for the fourth quarter of 2022, remained relatively flat, compared to 10% for the same period in 2021.

Net Income: Net income decreased by 70% to $1.5 billion in the fourth quarter of 2022, compared to the same period in 2021.

Earnings Per Share: Diluted EPS decreased by 68% to $3.61 in the fourth quarter of 2022, compared to the same period in 2021.

Full Year 2022

Revenue: Total revenue was $19.3 billion for the full year 2022, compared to $18.5 billion in 2021. Total revenue increased in 2022, primarily due to increased sales of the Company's COVID-19 vaccines. Product sales for 2022 were $18.4 billion, an increase of 4%, compared to 2021, primarily driven by a higher average selling price due to customer mix.

Cost of Sales: Cost of sales was $5.4 billion, or 29% of the product sales for 2022, including third-party royalties of $1.1 billion. Cost of sales, as a percentage of product sales, increased by 14 percentage points, from 15% in 2021. The increase was mainly due to a charge of $1.3 billion for inventory write-downs related to COVID-19 products that have exceeded or are expected to exceed their approved shelf-lives prior to being used, a loss on firm purchase commitments and related cancellation charges of $725 million, and an expense for unutilized manufacturing capacity and related contract manufacturing organization charges of $776 million. These charges are driven by overall lower demand, in particular from low-income countries, a shift in product demand to our Omicron-targeting COVID-19 bivalent boosters and costs associated with surplus production capacity.

Research and Development Expenses: Research and development expenses increased by 65% to $3.3

billion for 2022, compared to 2021. The growth in spending in 2022 was mainly due to increases in clinical trial expenses, clinical manufacturing expenses, personnel-related costs, and consulting and outside services, largely driven by the Company's late-stage clinical studies for the RSV, seasonal flu and CMV vaccine programs, as well as continued development of the Company's pipeline.

Selling, General and Administrative Expenses: Selling, general and administrative expenses increased by 100% to $1.1 billion for 2022, compared to 2021. The growth in spending in 2022 was mainly due to increases in consulting and outside services, marketing expense, and personnel-related costs, primarily attributable to the Company's continued corporate expansion, particularly in the commercial area and to a lesser extent, in support functions.

Provision for Income Taxes: The effective tax rate was 13% for 2022, compared to 8% for 2021. The increase in 2022 was primarily due to the benefit recorded in 2021 related to the release of the valuation allowance on the majority of our deferred tax assets.

Net Income: Net income decreased by 31% to $8.4 billion for the full year 2022, compared to 2021.

Earnings Per Share: Diluted EPS decreased by 29% to $20.12 for the full year 2022, compared to 2021.

Cash Position: Cash, cash equivalents and investments as of December 31, 2022 and December 31, 2021 were $18.2 billion and $17.6 billion, respectively.

Net Cash Provided By Operating Activities: Net cash provided by operating activities was $5.0 billion for the full year 2022, compared to $13.6 billion for the same period in 2021. Net cash provided by operating activities decreased in 2022, primarily attributable to revenue recognized from deferred revenue in excess of customer deposits received and increased income tax payments, partially offset by higher collection of receivables.

Cash Used for Purchases of Property, Plant and Equipment: Cash used for purchases of property and equipment was $400 million for the full year 2022, compared to $284 million for the same period in 2021. The increase was primarily driven by the Company’s continued business expansion of its manufacturing and research facilities.

Cash Used for Repurchases of Common Stock: Cash used for repurchases of common stock was $3.3 billion for the full year 2022. Moderna did not conduct share repurchases prior to the fourth quarter of 2021. From the end of the third quarter of 2021 to the end of the fourth quarter of 2022, the Company repurchased 27 million shares, reducing the number of common shares outstanding from 405 million to 385 million, more than offsetting 7 million shares of common stock issued in connection with equity compensation over this period.

2023 Financial Framework

Advance Purchase Agreements (APAs): The Company has COVID vaccine sales of approximately $5 billion currently contracted for 2023 delivery, with potential additional sales opportunities in the United States (endemic private and government markets), Europe, Japan, and other key markets. The Company expects product sales in the first half of 2023 of approximately $2.0 billion.

Cost of Sales: Cost of sales for the full year are expected to be in the range of 35-40% of sales, which includes approximately 5% of sales for combined royalties to Cellscript and NIAID.

Research & Development (R&D) and Selling, General & Administrative (SG&A) Expenses: Full-year expenses are expected to be approximately $6.0 billion, with approximately $4.5 billion in R&D.

Income Tax Provision: The Company expects a negligible provision for income taxes in 2023.

Capital Expenditures: The Company expects capital investments for 2023 of approximately $1.0 billion.

Share Repurchase Program
The $3 billion share repurchase program announced in February 2022 was completed early in the fourth quarter 2022. The Company has commenced repurchases from the additional $3 billion program announced in August 2022, and currently has $2.8 billion remaining under this latest authorization.

Corporate Updates

- **Continued Growth:** Moderna had approximately 3,900 employees as of December 31, 2022, compared to approximately 2,700 employees as of December 31, 2021.

- **Company Accolades**
    - Moderna named a Top Employer by *Science and Science Careers* for an eighth consecutive year.
    - Moderna named Top Employer by BioSpaces Best Places to Work for Second Consecutive Year.

- **Executive Committee Update**
    - Juan Andres, President, Strategic Partnerships has announced that he will retire from the Company in May 2023.
    - Moderna previously announced that Jerh Collins joined the Company in October as Chief Technical Operations and Quality Officer.
    - On December 7, Brad Miller was appointed Chief Information Officer of Moderna. At the same time, Marcello Damiani, who was serving in the role as Chief Digital Officer, announced that he would retire from the Company after seven and a half years.

Key 2023 Investor and Analyst Event Dates
- Vaccines Day: April 11
- 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 Thursday, February 23, 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/BI7d95b0c10db64ef48ce2960a272f006a
- **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 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 INCOME
(Unaudited, in millions, except per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Revenue:				
Product sales	$4,859	$6,935	$18,435	$17,675
Other revenue [1]	225	276	828	796
Total revenue	5,084	7,211	19,263	18,471
Operating expenses:				
Cost of sales	1,918	952	5,416	2,617
Research and development	1,211	648	3,295	1,991
Selling, general and administrative	375	201	1,132	567
Total operating expenses	3,504	1,801	9,843	5,175
Income from operations	1,580	5,410	9,420	13,296
Interest income	87	7	200	18
Other expense, net	(12)	(7)	(45)	(29)
Income before income taxes	1,655	5,410	9,575	13,285
Provision for income taxes	190	542	1,213	1,083
Net income	$1,465	$4,868	$8,362	$12,202
Earnings per share:				
Basic	$3.81	$12.03	$21.26	$30.31
Diluted	$3.61	$11.29	$20.12	$28.29
Weighted average common shares used in calculation of earnings per share:				
Basic	385	405	394	403
Diluted	405	431	416	431

MODERNA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in millions, except per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$3,205	$6,848
Investments	6,697	3,879
Accounts receivable	1,385	3,175
Inventory	949	1,441
Prepaid expenses and other current assets	1,195	728
Total current assets	13,431	16,071

Investments, non-current	8,318	6,843
Property, plant and equipment, net	2,018	1,241
Right-of-use assets, operating leases	121	142
Deferred tax assets	982	326
Other non-current assets	988	46
Total assets	$25,858	$24,669
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$487	$302
Accrued liabilities	2,101	1,472
Deferred revenue	2,038	6,253
Income taxes payable	48	876
Other current liabilities	249	225
Total current liabilities	4,923	9,128
Deferred revenue, non-current	673	615
Operating lease liabilities, non-current	92	106
Financing lease liabilities, non-current	912	599
Other non-current liabilities	135	76
Total liabilities	6,735	10,524
Stockholders' equity:		
Additional paid-in capital	1,173	4,211
Accumulated other comprehensive loss	(370)	(24)
Retained earnings	18,320	9,958
Total stockholders' equity	19,123	14,145
Total liabilities and stockholders' equity	$25,858	$24,669

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

	Years Ended December 31,	
	2022	**2021**
Operating activities		
Net income	$8,362	$12,202
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	226	142
Depreciation and amortization	348	232
Amortization/accretion of investments	31	54
Deferred income taxes	(559)	(318)
Other non-cash items	28	—
Changes in assets and liabilities:		
Accounts receivable	1,790	(1,784)
Prepaid expenses and other assets	(1,699)	(489)
Inventory	492	(1,394)
Right-of-use assets, operating leases	21	(58)
Accounts payable	240	204
Accrued liabilities	612	989
Deferred revenue	(4,157)	2,824
Income taxes payable	(828)	876
Operating lease liabilities	(14)	17
Other liabilities	88	123
Net cash provided by operating activities	4,981	13,620
Investing activities		
Purchases of marketable securities	(11,435)	(12,652)
Proceeds from maturities of marketable securities	3,151	1,338
Proceeds from sales of marketable securities	3,548	3,105
Purchases of property, plant and equipment	(400)	(284)
Investment in convertible notes and equity securities	(40)	(30)
Net cash used in investing activities	(5,176)	(8,523)
Financing activities		
Proceeds from issuance of common stock through equity plans	65	124
Repurchase of common stock	(3,329)	(857)
Changes in financing lease liabilities	(184)	(140)
Net cash used in financing activities	(3,448)	(873)
Net (decrease) increase in cash, cash equivalents and restricted cash	(3,643)	4,224
Cash, cash equivalents and restricted cash, beginning of year	6,860	2,636
Cash, cash equivalents and restricted cash, end of period	$3,217	$6,860

[1] Includes grant revenue and collaboration revenue

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) in the first half of 2023; timing for review of the mRNA-1010 (seasonal flu) Phase 3 interim efficacy analysis; the repurchase by Moderna of shares of its common stock under its repurchase programs; Moderna's collaboration with Merck to jointly develop and commercialize mRNA-4157/V940, plans to initiate a Phase 3 in adjuvant melanoma in 2023 and plans to expand into additional cancer types; timing for presentation of full data from the Phase 2 study of mRNA-4157/V940; plans for dose selection and study expansion for Moderna's propionic acidemia therapeutic; and Moderna's 2023 financial framework, including Moderna's anticipated spending on R&D in 2023. 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, 2021 and Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022, each 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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