

Moderna Reports Second Quarter 2024 Financial Results and Provides Business Updates

Reports second quarter revenues of \$241 million, GAAP net loss of \$1.3 billion and GAAP EPS of \$(3.33)

Updates 2024 financial framework and revises expectations for product sales to \$3.0 to \$3.5 billion

Received U.S. FDA approval for RSV vaccine, mRESVIA, and began shipping in July; received EMA positive opinion in June

Announced positive Phase 3 data for combination vaccine against influenza and COVID-19

Announced positive Phase 3 data for next-generation COVID-19 vaccine

CAMBRIDGE, MA / ACCESSWIRE / August 1, 2024 / Moderna, Inc. (NASDAQ:MRNA) today reported financial results and provided business updates for the second quarter of 2024.

“During the second quarter, we marked the approval of our second mRNA product and significantly lowered our operating costs. We remain focused on execution for the 2024-25 COVID season and the launch of our RSV vaccine in the U.S.,” said Stéphane Bancel, Chief Executive Officer of Moderna. “With continued positive Phase 3 data across our respiratory portfolio, we are using our mRNA platform to address significant unmet medical needs and advance public health. Our platform is poised to reach millions globally this year and we are excited by its continued positive impact on patients.”

Recent progress includes:

Commercial Updates

COVID-19: The Company reported \$184 million in Spikevax® (COVID-19 vaccine) sales in the second quarter of 2024, which includes \$162 million of U.S. sales and \$22 million of international sales.

Contracting is mostly complete in a highly competitive COVID market. Moderna is ready for the upcoming vaccination season with ample and timely supply. In the U.S., the majority of contracts are finalized and Moderna’s focus is on working with public health officials, health care providers and pharmacies to drive vaccination coverage rates to reduce the substantial burden of COVID-19. In the European Union (EU), Moderna is negotiating a tender framework agreement to provide market access; however, based on recent discussions, the Company now expects very low EU sales in 2024. In the Rest of World, the Company has multiple signed contracts in place, with some potential revenue deferrals into 2025.

RSV: Following U.S. Food and Drug Administration (FDA) approval in May and the Advisory Committee on Immunization Practices (ACIP) recommendation in June, Moderna's RSV vaccine, mRESVIA®, has launched in the U.S. and deliveries are underway as of July 2024. The Company is targeting the pharmacy segment in the U.S. and its commercial focus is on reaching vaccinators in a highly competitive market. Additionally, the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorization in the EU for mRESVIA.

Second Quarter 2024 Financial Results

Revenue: Total revenue for the second quarter of 2024 was \$241 million, compared to \$344 million in the same period in 2023. This decline was primarily attributable to decreased sales of the Company's COVID-19 vaccine. Net product sales for the second quarter of 2024 were \$184 million, reflecting a 37% decrease compared to the same period in 2023. This reduction aligns with the expected shift to a seasonal COVID-19 vaccine market, with higher demand anticipated in the fall and winter. In the prior year period, product sales were largely recognized from doses delivered and deferred from 2022.

Cost of Sales: Cost of sales for the second quarter of 2024 was \$115 million, which included third-party royalties of \$10 million, unutilized manufacturing capacity and wind-down costs of \$55 million, and inventory write-downs of \$14 million. Compared to the same period in 2023, the cost of sales decreased by \$616 million, or 84%. Cost of sales as a percentage of net product sales was 62% for the second quarter of 2024, down from 249% in the second quarter of 2023. The reduction in cost of sales was primarily due to a lower sales volume and decreased unutilized manufacturing capacity, inventory write-downs, and losses on firm purchase commitments and related cancellation fees. The reduction in cost of sales as a percentage of net product sales in 2024 was mainly driven by lower costs, partially offset by the reduced sales volume, reflecting a decline in product demand and increased product seasonality.

Research and Development Expenses: Research and development expenses for the second quarter of 2024 increased by 6% to \$1.2 billion, compared to the second quarter in 2023. This increase was mainly due to higher personnel-related costs, driven by an increased headcount to support ongoing research and development efforts. Research and development expenses for the quarter also include the purchase of a priority review voucher. The increase was partly offset by a decrease in clinical development and manufacturing expenses, resulting from lower spending on clinical trials for the Company's COVID-19 and seasonal flu programs, in line with its planned trial schedules.

Selling, General and Administrative Expenses: Selling, general and administrative expenses for the second quarter of 2024 decreased by 19% to \$268 million, compared to the second quarter in 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: The Company did not recognize an income tax expense for the second quarter of 2024, in contrast to an income tax benefit of \$369 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 Loss: Net loss was \$(1.3) billion for the second quarter of 2024, compared to \$(1.4) billion for the second quarter of 2023.

Net Loss Per Share: Net loss per share was \$(3.33) for the second quarter of 2024, compared to \$(3.62) for the second quarter of 2023.

Cash Position: Cash, cash equivalents and investments as of June 30, 2024, were \$10.8 billion, compared to \$12.2 billion as of March 31, 2024. The decrease in the cash position during the second quarter of 2024 was largely attributable to research and development expenses and operating activities.

2024 Financial Framework

Net Sales: The Company revises its 2024 expected net product sales to \$3.0 to \$3.5 billion from its respiratory franchise. For the second half of the year, it expects a sales split of 40-50% in the third quarter with the balance in the fourth quarter of 2024, subject to the timing of regulatory approvals. The update in product sales is driven by three primary factors: very low EU sales in 2024, potential revenue deferrals for certain international sales into 2025, and an increasingly competitive environment for respiratory vaccines in the U.S.

Cost of Sales: Cost of sales is expected to be in the range of 40-50% 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

Respiratory vaccines:

- **Respiratory syncytial virus (RSV) vaccine:** After Moderna received U.S. FDA approval for its RSV vaccine (mRNA-1345), ACIP issued a recommendation for all unvaccinated people 75 years of age and older and unvaccinated people ages 60-74 who are at increased risk for RSV to receive the vaccine for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) and acute respiratory disease (ARD). Additionally, the EMA adopted a positive opinion recommending marketing authorization in the EU for mRESVIA. **The Company is awaiting regulatory approvals in additional countries.**
- **Seasonal flu vaccine:** Moderna's seasonal flu vaccine (mRNA-1010) demonstrated consistently acceptable safety and tolerability across three Phase 3 trials. **The Company is engaging 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) has met its primary efficacy endpoint, demonstrating non-inferior vaccine efficacy against COVID-19 compared to Spikevax (mRNA-1273) in participants 12 years of age and older. Higher efficacy was also observed compared to Spikevax in adults 18 years of age and older. **The Company is engaging with regulators and intends to file in 2024.**
- Seasonal flu + COVID vaccine: Moderna recently announced the Phase 3 trial of its combination vaccine against seasonal flu and COVID-19 (mRNA-1083) has met its primary endpoints, eliciting higher immune responses against influenza virus and SARS-CoV-2 than licensed flu and COVID vaccines in adults 50 years and older, including an enhanced influenza vaccine in adults 65 years and older. **The Company is engaging with regulators on next steps.**

Oncology therapeutics:

- Individualized Neoantigen Therapy (INT): Moderna and Merck announced additional 3-year data for mRNA-4157 in combination with KEYTRUDA® (pembrolizumab), demonstrating sustained improvement in recurrence-free survival and distant metastasis-free survival versus KEYTRUDA in patients with high-risk stage III/IV melanoma following complete resection. At a median planned follow-up of the Phase 2b study at 34.9 months, mRNA-4157 in combination with KEYTRUDA reduced the risk of recurrence or death by 49% and the risk of distant metastasis or death by 62% compared to KEYTRUDA alone in these patients. The 2.5-year recurrence-free survival rate of mRNA-4157 in combination with KEYTRUDA was 74.8% as compared to 55.6% for KEYTRUDA alone, with the benefit observed across exploratory subgroups.

Rare disease therapeutics:

- Methylmalonic acidemia (MMA) therapeutic: Moderna's investigational therapeutic for MMA (mRNA-3705) has been selected by the U.S. FDA for the Support for Clinical Trials Advancing Rare Disease Therapeutics (START) pilot program. mRNA-3705 was chosen by the Center for Biologics Evaluation and Research (CBER) as one of four investigational medicines for accelerated development to address unmet medical needs for rare diseases. **The Company expects to advance its MMA program into a registrational study in 2024.**

Moderna Corporate Updates

- Announced that David M. Rubenstein, Co-Founder and Co-Chairman of The Carlyle Group, will join Moderna's Board of Directors, effective August 5, 2024, when directors Robert Langer and Stephen Berenson will retire from the Board.
- Entered into an agreement with Mitsubishi Tanabe Pharma Corporation to promote Moderna's mRNA respiratory vaccine portfolio in Japan.
- Received a project award of \$176 million through BARDA's Rapid Response Partnership Vehicle Consortium to accelerate the development of an mRNA-based pandemic influenza vaccine.
- Published third annual ESG Report, Impacting Human Health, on June 25, 2024.

Company Accolades

- Moderna was named to the *Boston Business Journal's* annual list of the Most Charitable Companies in Massachusetts (second consecutive year)
- Moderna was recognized as a top-scoring company on Disability:IN's Disability Equality Index and a Best Place to Work for Disability Inclusion (third consecutive year)
- Moderna was recognized as a Great Place to Work in the U.S. by Great Place To Work® (second consecutive year)

Key 2024 Investor and Analyst Event Dates

- 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 August 1, 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/BI2ef72dcc8f6e4477bf2f61ab92054abb>
- **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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Net product sales	\$ 184	\$ 293	\$ 351	\$ 2,121
Other revenue ¹	57	51	57	85
Total revenue	241	344	408	2,206
Operating expenses:				
Cost of sales	115	731	211	1,523
Research and development	1,221	1,148	2,284	2,279
Selling, general and administrative	268	332	542	637
Total operating expenses	1,604	2,211	3,037	4,439
Loss from operations	(1,363)	(1,867)	(2,629)	(2,233)
Interest income	111	104	231	213
Other (expense) income, net	(27)	14	(46)	(34)
Loss before income taxes	(1,279)	(1,749)	(2,444)	(2,054)
Provision for (benefit from) income taxes	—	(369)	10	(753)
Net loss	\$ (1,279)	\$ (1,380)	\$ (2,454)	\$ (1,301)
Net loss per share:				
Basic and diluted	\$ (3.33)	\$ (3.62)	\$ (6.41)	\$ (3.39)
Weighted average common shares used in calculation of net loss per share:				
Basic and diluted	384	381	383	383

¹Includes grant, collaboration and licensing and royalty revenue

MODERNA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in millions)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,478	\$ 2,907
Investments	6,010	5,697
Accounts receivable, net	163	892
Inventory	399	202
Prepaid expenses and other current assets	611	627
Total current assets	9,661	10,325
Investments, non-current	2,326	4,677
Property, plant and equipment, net	2,196	1,945
Right-of-use assets, operating leases	775	713
Deferred tax assets	81	81
Other non-current assets	641	685
Total assets	<u>\$ 15,680</u>	<u>\$ 18,426</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 279	\$ 520
Accrued liabilities	1,333	1,798
Deferred revenue	702	568
Income taxes payable	7	63
Other current liabilities	42	66
Total current liabilities	2,363	3,015
Deferred revenue, non-current	95	83
Operating lease liabilities, non-current	668	643
Financing lease liabilities, non-current	576	575
Other non-current liabilities	266	256
Total liabilities	3,968	4,572
Stockholders' equity:		
Additional paid-in capital	631	371
Accumulated other comprehensive loss	(71)	(123)
Retained earnings	11,152	13,606
Total stockholders' equity	11,712	13,854
Total liabilities and stockholders' equity	<u>\$ 15,680</u>	<u>\$ 18,426</u>

MODERNA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in millions)

	Six Months Ended June 30,	
	2024	2023
Operating activities		
Net loss	\$ (2,454)	\$ (1,301)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	213	149
Depreciation and amortization	77	170
Amortization/accretion of investments	(55)	(29)
Loss (gain) on equity investments, net	35	(17)
Deferred income taxes	—	(530)
Other non-cash items	7	(12)
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable, net	729	1,153
Prepaid expenses and other assets	3	(142)
Inventory	(197)	234
Right-of-use assets, operating leases	(62)	(9)
Accounts payable	(199)	(187)
Accrued liabilities	(464)	(633)
Deferred revenue	146	(979)
Income taxes payable	(56)	(1)
Operating lease liabilities	25	12
Other liabilities	(11)	(18)
Net cash used in operating activities	(2,263)	(2,140)
Investing activities		
Purchases of marketable securities	(3,390)	(1,281)
Proceeds from maturities of marketable securities	3,536	3,264
Proceeds from sales of marketable securities	1,999	2,427
Purchases of property, plant and equipment	(378)	(347)
Acquisition of business, net of cash acquired	—	(85)
Investment in convertible notes and equity securities	—	(23)
Net cash provided by investing activities	1,767	3,955
Financing activities		
Proceeds from issuance of common stock through equity plans	47	25
Repurchase of common stock, including excise tax	—	(1,154)
Changes in financing lease liabilities	1	(81)
Net cash provided by (used in) financing activities	48	(1,210)
Net (decrease) increase in cash, cash equivalents and restricted cash	(448)	605
Cash, cash equivalents and restricted cash, beginning of year	2,928	3,217
Cash, cash equivalents and restricted cash, end of period	\$ 2,480	\$ 3,822

Spikevax® and mRESVIA® are registered trademarks of Moderna.
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 updated COVID-19 and RSV vaccines and related market dynamics; 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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