Moderna Reports Third Quarter 2024 Financial Results and Provides Business Updates

Reports third quarter revenues of $1.9 billion, GAAP net income of $13 million and GAAP EPS of $0.03

Achieves year-to-date product sales of $2.2 billion; reiterates 2024 expected product sales of $3.0 to $3.5 billion

Initiated dosing in two pivotal Phase 3 trials to assess efficacy of investigational mRNA vaccines against norovirus and influenza

Announces expansion of its Executive Committee

CAMBRIDGE, MA / ACCESSWIRE / November 7, 2024 / Moderna, Inc. (NASDAQ:MRNA) today reported financial results and provided business updates for the third quarter of 2024.

"During the third quarter, we focused on execution with the launch of our updated COVID-19 and RSV vaccines in markets across the globe. I am pleased with the cost efficiency we achieved in the quarter, tracking ahead of where we planned to be at this time," said Stéphane Bancel, Chief Executive Officer of Moderna. "Looking into the fourth quarter and preparing for 2025, we remain focused on driving sales growth, delivering 10 product approvals over the next three years, and continuing to reduce our cost structure."

Recent progress includes:

Commercial Updates

COVID-19: The Company reported $1.8 billion in Spikevax® sales in the third quarter of 2024, which includes $1.2 billion of U.S. sales and $0.6 billion of international sales.

Moderna's updated mRNA COVID-19 vaccine has been approved in major markets worldwide. In the U.S., the Company was ready for an earlier COVID vaccine approval compared to the prior season, with timely shipments to all channels across the U.S. healthcare system. The approval timing has driven an earlier uptake in the retail channel, where Moderna has 40% market share season to date.[1]

The Company continues to focus on public health efforts to drive vaccination rates globally. Moderna has undertaken marketing and awareness campaigns to educate consumers and activate the medical community. The recent recommendation of the CDC's Advisory Committee on Immunization Practices (ACIP) of additional doses for older adults and high-risk populations is supportive of vaccination uptake.

[1] Source: Based on information licensed from IQVIA: IQVIA RAPID Weekly Audit for August-October 2024, reflecting estimates of real-world activity. All rights reserved.

RSV: The Company reported $10 million in mRESVIA® sales in the third quarter of 2024. Sales were lower than anticipated, resulting from the approval and recommendation of mRESVIA later in the contracting season, when many customers had completed their orders. Moderna's RSV vaccine has been approved in the U.S., EU, Norway, Iceland and Qatar.

Third Quarter 2024 Financial Results

Revenue: Total revenue for the third quarter of 2024 was $1.9 billion, compared to $1.8 billion in the same period in 2023. Net product sales for the third quarter of 2024 reached $1.8 billion, reflecting a 4% year-over-year increase. This growth was primarily driven by higher sales in the U.S. market, following the earlier launch of the updated COVID-19 vaccine. With FDA approval granted three weeks earlier than in the previous year, the Company was able to meet demand more effectively. International sales were lower compared to the same period in 2023, when sales benefited from the fulfillment of orders deferred from 2022. Additionally, the Company commenced sales of its RSV vaccine during the third quarter of 2024. RSV vaccine sales were $10 million in the quarter.

Cost of Sales: Cost of sales for the third quarter of 2024 was $514 million, which included third-party royalties of $92 million, inventory write-downs of $214 million, and unutilized manufacturing capacity and wind-down costs of $27 million. Compared to the same period in 2023, the cost of sales decreased by $1.7 billion, or 77%. Cost of sales as a percentage of net product sales was 28% for the third quarter of 2024, down from 128% in the third quarter of 2023. The significant decrease in both cost of sales and cost of sales as a percentage of net product sales was primarily due to reductions in inventory write-downs and unutilized manufacturing capacity, and productivity improvements.

Research and Development Expenses: Research and development expenses for the third quarter of 2024 decreased by 2% to $1.1 billion, compared to the third quarter in 2023. The reduction was mainly due to lower clinical development and manufacturing expenses, driven by decreased spending on clinical trials and productivity improvements. This decrease was partially offset by the cost of purchasing a priority review voucher.

Selling, General and Administrative Expenses: Selling, general and administrative expenses for the third quarter of 2024 decreased by 36% to $281 million, compared to the third quarter in 2023. This reduction was driven by the Company's continued focus on cost management and operational efficiencies achieved through prior investments in foundational capabilities. These efficiencies significantly reduced reliance on external consultants and purchased services. The Company remains committed to investing in digital and commercial capabilities and has increased its emphasis on building and utilizing AI technologies to further streamline operations and enhance productivity.

Income Taxes: The Company recognized an income tax expense of $8 million for the third quarter of 2024, compared to $1.7 billion in the same period last year. The significant decrease was primarily due to the establishment of a $1.7 billion valuation allowance on deferred tax assets in the third quarter of 2023. This valuation allowance has been applied consistently since its initial recognition in the third quarter of 2023.

Net Income (Loss): Net income was $13 million for the third quarter of 2024, compared to a net loss of $(3.6) billion for the third quarter of 2023.

Earnings (Loss) Per Share: Earnings per share was $0.03 for the third quarter of 2024, compared to loss per share of $(9.53) for the third quarter of 2023.

Cash Position: Cash, cash equivalents and investments as of September 30, 2024, were $9.2 billion, compared to $10.8 billion as of June 30, 2024. The decrease in the cash position during the third quarter of 2024 was largely attributable to research and development expenses and operating activities.

2024 Financial Framework

Net Sales: The Company reiterates its 2024 expected net product sales of $3.0 to $3.5 billion from its respiratory franchise.

Cost of Sales: Cost of sales is now expected to be in the range of 40-45% of product sales for the year (previously 40-50%).

Research and Development Expenses: Full-year 2024 research and development expenses are now anticipated to be in the range of $4.6 to $4.7 billion (previously $4.8 billion).

Selling, General and Administrative Expenses: Selling, general and administrative expenses for 2024 are projected to be approximately $1.2 billion.

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

Capital Expenditures: Capital expenditures for 2024 are now expected to be approximately $1.2 billion (previously ~$0.9 billion). The updated estimate includes the purchase of the Norwood, MA, campus for ~$0.4 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

The Company remains focused on a prioritized research and development portfolio, delivering on 10 product approvals over the next three years.

Respiratory vaccines:

- Next-generation COVID-19 vaccine: Moderna shared positive Phase 3 vaccine efficacy and immunogenicity data for its next-generation COVID-19 vaccine (mRNA-1283) at its R&D Day event in September 2024.

- Respiratory syncytial virus (RSV) vaccine: Moderna shared positive Phase 3 data for its vaccine against RSV (mRNA-1345) in high-risk adults aged 18-59 at its 2024 R&D Day event.

- Seasonal flu + COVID vaccine: Moderna shared positive Phase 3 immunogenicity data for its flu/COVID combination vaccine at its 2024 R&D Day event.

- Seasonal flu vaccine: The Company has initiated a Phase 3 efficacy study (P304) for its seasonal flu vaccine (mRNA-1010), which has demonstrated consistently acceptable safety and tolerability across three previous Phase 3 trials.

- **Moderna is on track to file in 2024 for approval of its next-generation COVID-19 vaccine (mRNA-1283) and RSV vaccine (mRNA-1345) for high-risk adults aged 18-59; the Company expects to communicate the PDUFA date for each of these programs when it is confirmed. Moderna intends to use priority review vouchers for mRNA-1283 and mRNA-1345 for high-risk adults aged 18-59. For its flu/COVID combination vaccine (mRNA-1083), the Company intends to file in 2024, subject to ongoing discussions with the U.S. FDA, and has decided not to use a priority review voucher.**

Latent and other vaccines:

- Cytomegalovirus (CMV) vaccine: Moderna expects to have accrued the 81 cases necessary to trigger the first interim analysis of the Phase 3 vaccine efficacy study of its CMV vaccine candidate (mRNA-1647) by the end of 2024. If the Data and Safety Monitoring Board (DSMB) recommends unblinding at the first interim analysis, the Company intends to share the results.

- Norovirus vaccine: Moderna's trivalent vaccine candidate for the prevention of norovirus (mRNA-1403) advanced into a pivotal Phase 3 randomized clinical trial evaluating its efficacy, safety and immunogenicity.

Oncology therapeutics:

- Individualized Neoantigen Therapy (INT): Moderna and Merck initiated a Phase 3 study evaluating adjuvant INT (mRNA-4157) in combination with KEYTRUDA® after neoadjuvant KEYTRUDA and chemotherapy in patients with certain types of resected non-small cell lung cancer. This is the third Phase 3 trial for the investigational INT focused on earlier stages of cancer.

Rare disease therapeutics:

- Propionic acidemia (PA) therapeutic: In an ongoing Phase 1/2 study designed to evaluate safety and pharmacology in trial participants with PA, Moderna's investigational therapeutic (mRNA-3927) was generally well-tolerated to date with no events meeting protocol-defined dose-limiting toxicity criteria. Early results suggest potential decreases in annualized metabolic decompensation event (MDE) frequency compared to pre-treatment, and the majority of patients have elected to continue on the open label extension study. **The Company intends to begin generating pivotal trial data in 2024.**

- 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. The FDA and Moderna have agreed on the pivotal study design. **The Company expects to start a pivotal study in the first half of 2025.**

Moderna Corporate Updates

- Expanded the Moderna Executive Committee:
    - Moderna President Stephen Hoge, M.D., has taken on an expanded role, adding new responsibilities overseeing Moderna’s commercial organization. As President, Dr. Hoge will now be responsible for strategy across Research and Development, Medical Affairs and Commercial.
    - Rose Loughlin, Ph.D., has been promoted to Executive Vice President, Research, and will lead Moderna's research organization. Dr. Loughlin will join the Executive Committee and report to Chief Executive Officer Stéphane Bancel.
    - Jacqueline Miller, M.D., has been promoted to Chief Medical Officer, and will lead Moderna's development organization. Dr. Miller will join the Executive Committee and report to Chief Executive Officer Stéphane Bancel.
    - Moderna Chief Human Resources Officer Tracey Franklin has expanded her role to Chief People and Digital Technology Officer, overseeing the Company’s talent and digital functions. Brad Miller, Chief Information Officer of Moderna, will report to Franklin in her newly expanded role.
- Entered into a purchase and sale agreement for the properties the Company currently leases in Norwood, Massachusetts, where the Moderna Technology Center (MTC) is located. The

purchase of this highly strategic asset for Moderna operations gives the Company full control to build out the campus for future productivity and innovation.
- Announced that Abbas Hussain, former Chief Executive Officer of Vifor Pharma, joined Moderna's Board of Directors, effective October 2, 2024.
- Entered into a joint agreement with Cenra Healthcare to promote Moderna's mRNA respiratory vaccine portfolio in Taiwan, including COVID-19 vaccines.
- Announced its manufacturing facility in Laval, Quebec, has been granted a Drug Establishment License from Health Canada, enabling the site to become fully operational.
- Partnered with Coursera to launch a free course on mRNA technology.

Company Accolades

- Moderna was ranked as a top employer in the global biopharmaceutical industry by *Science* on the Science Careers' 2024 Top Employers Survey (tenth consecutive year)

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on November 7, 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/BIfd5a9d864ef1471c805e19b231f7d939
- **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.

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in millions, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Net product sales	$ 1,820	$ 1,757	$ 2,171	$ 3,878
Other revenue[1]	42	74	99	159
Total revenue	1,862	1,831	2,270	4,037
Operating expenses:				
Cost of sales	514	2,241	725	3,764
Research and development	1,137	1,160	3,421	3,439
Selling, general and administrative	281	442	823	1,079
Total operating expenses	1,932	3,843	4,969	8,282
Loss from operations	(70)	(2,012)	(2,699)	(4,245)
Interest income	103	105	334	318
Other expense, net	(12)	(51)	(58)	(85)
Income (loss) before income taxes	21	(1,958)	(2,423)	(4,012)
Provision for income taxes	8	1,672	18	919
Net income (loss)	$ 13	$ (3,630)	$ (2,441)	$ (4,931)
Earnings (loss) per share:				
Basic	$ 0.03	$ (9.53)	$ (6.37)	$ (12.89)
Diluted	$ 0.03	$ (9.53)	$ (6.37)	$ (12.89)
Weighted average common shares used in calculation of earnings (loss) per share:				
Basic	385	381	383	382
Diluted	399	381	383	382

[1]Includes grant, collaboration and licensing and royalty revenue

MODERNA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in millions)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 1,644	$ 2,907
Investments	5,223	5,697
Accounts receivable, net	1,564	892
Inventory	412	202
Prepaid expenses and other current assets	823	627
Total current assets	9,666	10,325
Investments, non-current	2,335	4,677
Property, plant and equipment, net	2,381	1,945
Right-of-use assets, operating leases	784	713
Deferred tax assets	82	81
Other non-current assets	555	685
Total assets	$ 15,803	$ 18,426
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 373	$ 520
Accrued liabilities	1,376	1,798
Deferred revenue	379	568
Income taxes payable	4	63
Other current liabilities	69	66
Total current liabilities	2,201	3,015
Deferred revenue, non-current	95	83
Operating lease liabilities, non-current	679	643
Financing lease liabilities, non-current	625	575
Other non-current liabilities	276	256
Total liabilities	3,876	4,572
Stockholders' equity:		
Additional paid-in capital	751	371
Accumulated other comprehensive income (loss)	11	(123)
Retained earnings	11,165	13,606
Total stockholders' equity	11,927	13,854
Total liabilities and stockholders' equity	$ 15,803	$ 18,426

MODERNA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in millions)

	Nine Months Ended September 30,	
	2024	2023
Operating activities		
Net loss	$ (2,441)	$ (4,931)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	325	226
Depreciation and amortization	129	419
Amortization/accretion of investments	(76)	(41)
Loss on equity investments, net	43	16
Deferred income taxes	—	934
Other non-cash items	6	25
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable, net	(672)	(481)
Prepaid expenses and other assets	(147)	772
Inventory	(208)	462
Right-of-use assets, operating leases	(63)	(657)
Accounts payable	(103)	(8)
Accrued liabilities	(415)	63
Deferred revenue	(177)	(1,173)
Income taxes payable	(58)	8
Operating lease liabilities	33	605
Other liabilities	(5)	21
Net cash used in operating activities	(3,829)	(3,740)
Investing activities		
Purchases of marketable securities	(4,641)	(2,097)
Proceeds from maturities of marketable securities	4,648	4,711
Proceeds from sales of marketable securities	3,010	2,725
Purchases of property, plant and equipment	(529)	(487)
Acquisition of business, net of cash acquired	—	(85)
Investment in convertible notes and equity securities	—	(23)
Net cash provided by investing activities	2,488	4,744
Financing activities		
Proceeds from issuance of common stock through equity plans	55	31
Repurchase of common stock, including excise tax	—	(1,153)
Changes in financing lease liabilities	4	(146)
Net cash provided by (used in) financing activities	59	(1,268)
Effect of changes in exchange rates on cash and cash equivalents	1	—
Net decrease in cash, cash equivalents and restricted cash	(1,281)	(264)
Cash, cash equivalents and restricted cash, beginning of year	2,928	3,217
Cash, cash equivalents and restricted cash, end of period	$ 1,647	$ 2,953

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: market dynamics for Moderna's COVID-19 and RSV vaccines, including Moderna's market share; Moderna's ability to drive vaccination rates; Moderna's ability to effectively leverage AI technologies; Moderna's 2024 financial framework and anticipated performance, including expected product sales; Moderna's ability to deliver 10 product approvals over the next three years; and anticipated milestones for Moderna's pipeline programs in 2024, including Moderna's intent to file for regulatory approval for certain respiratory vaccines. 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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