



NEWS RELEASE

Moderna Reports Second Quarter 2023 Financial Results and Provides Business Updates

8/3/2023

Second quarter 2023 revenues of \$0.3 billion; net loss of \$1.4 billion and loss per share of \$3.62

Company expecting 2023 COVID-19 vaccine sales of \$6 billion to \$8 billion, dependent on U.S. vaccination rates

Company submitted its investigational RSV vaccine to several regulators globally ahead of potential 2024 launch

With its partner Merck, the Company began Phase 3 trial of mRNA-4157, its individualized neoantigen therapy (INT), in combination with Keytruda®, for high-risk melanoma

CAMBRIDGE, MA / ACCESSWIRE / August 3, 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 second quarter of 2023.

"Second quarter sales were on target, given the seasonal nature of Covid. I am pleased with the progress our U.S. commercial team has made to get new contracts in place for fall 2023. We are on track to deliver 2023 sales between \$6 billion to \$8 billion, depending on Covid vaccination rates in the U.S.," said Stéphane Bancel, Chief Executive Officer of Moderna. "Our late-stage clinical pipeline is firing on all cylinders with four infectious disease vaccines in Phase 3, including RSV which was recently submitted to regulators for approval. Our individualized neoantigen therapy is now in Phase 3 for melanoma and our lead rare disease program for PA is in dose confirmation. We believe that all these products should launch in 2024, 2025 or 2026, and we are continuing to invest in scaling Moderna to bring forward an unprecedented number of innovative mRNA medicines for patients."



Recent progress includes:

Respiratory Vaccines

COVID-19

The Company presented clinical data at the June VRBPAC meeting demonstrating potent neutralization and cross-reactivity with its monovalent XBB.1.5 vaccine, mRNA-1273.815. Similar neutralization was seen for XBB.1.5, XBB.1.16, and XBB.2.3.2 sub-variants. Following the FDA's recommendation for a monovalent SARS-CoV-2 XBB lineage vaccine, which aligns with other regulators and global public health agencies, Moderna has submitted its updated COVID-19 vaccine to regulators globally for approval or authorization and is ready for fall vaccination season with ample and timely supply.

RSV

Moderna has submitted marketing authorization applications globally for mRNA-1345, a vaccine for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) and acute respiratory disease (ARD) in adults aged 60 years or older.

The regulatory applications are based on positive data from a prespecified interim analysis of the pivotal ConquerRSV study, a randomized, double-blind, placebo-controlled study of approximately 37,000 adults 60 years or older in 22 countries. The primary efficacy endpoints were based on two definitions of RSV-LRTD, defined as either two or more symptoms or three or more symptoms of disease. The trial met both its primary efficacy endpoints, with a vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; $p < 0.0001$) against RSV-LRTD as defined by two or more symptoms, and a VE of 82.4% (96.36% CI: 34.8%, 95.3%; $p = 0.0078$) against RSV-LRTD defined by three or more symptoms. In addition to older adults, mRNA-1345 is being investigated in a fully enrolled, ongoing Phase 1 trial in pediatric populations. No cases of Guillain-Barre Syndrome (GBS) had been reported with mRNA-1345 in the Phase 3 RSV trial as of the April 30 th cutoff date.

Flu

Enrollment has been successfully completed in the Company's Phase 3 immunogenicity trial (P303) for an enhanced formulation of mRNA-1010. This updated formulation is anticipated to generate an improved immune response to influenza B strains and is intended to enable licensure of mRNA-1010 through accelerated approval. The Company expects to share an update on P303 in the third quarter of 2023.

Latent Virus Vaccines

Cytomegalovirus (CMV)

The pivotal Phase 3 study of Moderna's CMV vaccine candidate (mRNA-1647), known as CMVictory, is ongoing, with enrollment more than 80% complete.

Epstein-Barr virus (EBV)

Enrollment is complete (350 healthy EBV-seropositive adults), and dosing continues in the Phase 1 trial of mRNA-1195 designed to evaluate safety, reactogenicity, and immunogenicity. mRNA-1195 is a therapeutic vaccine candidate designed to prevent longer-term sequelae of EBV infection, such as multiple sclerosis and post-transplant lymphoproliferative disease (PTLD). Enrollment is ongoing for the Phase 1 trial of mRNA-1189 aimed at preventing infectious mononucleosis (IM).

Therapeutics

Immuno-oncology

Merck and Moderna announced the initiation of a pivotal Phase 3 global, randomized, double-blind, placebo- and active-comparator-controlled study (V940-001) to evaluate the safety and efficacy of mRNA-4157 (V940) in combination with KEYTRUDA in people with resected high-risk (Stage IIB-IV) melanoma compared to KEYTRUDA alone. The trial is slated to enroll approximately 1,089 patients at more than 165 sites in over 25 countries. The primary endpoint of the study is recurrence-free survival (RFS), and secondary endpoints include distant metastasis-free survival (DFMS), overall survival (OS) and safety. Moderna and Merck plan to expand the development program to additional tumor types, including non-small cell lung cancer (NSCLC).

Rare diseases

Propionic Acidemia (PA)

The ongoing global Phase 1/2 clinical trial of mRNA-3927 is ongoing and currently enrolling patients in the dose confirmation arm. This trial includes a dose optimization stage (cohorts 1 through 5) followed by a dose confirmation stage with progression dependent on the safety of the preceding cohort. Enrollment is complete for cohorts 1 through 5. mRNA-3927 has been well-tolerated at the doses administered, with encouraging early signs of dose-dependent pharmacology and potential clinical benefit. The majority of eligible participants have elected to continue with treatment by participating in the Open-Label Extension Study. Interim data was presented at the American Society of Gene & Cell Therapy (ASGCT) on May 18, 2023.

Methylmalonic acidemia (MMA)

The Phase 1 trial evaluating the safety and pharmacology of mRNA-3705 in patients 1 year of age and older with MMA in a multiple ascending dose study is ongoing and enrolling patients in the fourth cohort.

Second Quarter 2023 Financial Results

Revenue: Total revenue for the second quarter of 2023 was \$344 million, compared to \$4.7 billion in the same period in 2022, mainly due to a decrease in sales of the Company's COVID-19 vaccine. Product sales for the second quarter of 2023 were \$293 million, a decrease of 94% compared to the same period in 2022, primarily driven by lower sales volume.

Cost of Sales: Cost of sales for the second quarter of 2023 was \$731 million. In addition to unit driven manufacturing costs, this includes royalties of \$12 million and the following charges: \$464 million for inventory write-downs related to excess and obsolete COVID-19 product, unutilized manufacturing capacity of \$135 million, and losses on firm purchase commitments of \$75 million. These charges, other than royalties, were primarily driven by a shift in product demand to our latest monovalent XBB.1.5 COVID-19 vaccine candidate as well as a decline in customer demand. The shift from a bivalent to monovalent strain selection rendered the remaining mRNA-1273.222 product inventory obsolete. Cost of sales as a percent of product sales was 249% of product sales, compared to 30% in the second quarter of 2022. The increase was driven by the aforementioned charges over lower product sales compared to the prior year, driven by a decline in product demand and increased product seasonality.

Research and Development Expenses: Research and development expenses for the second quarter of 2023 increased by 62% 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.

Selling, General and Administrative Expenses: Selling, general and administrative expenses for the second quarter of 2023 increased by 57% to \$332 million, in comparison to the second quarter of 2022. The growth in spending was primarily due to increases in outside services spend and personnel-related costs, primarily driven by increased headcount and spend in digital, medical affairs and commercial functions in support of the Company's digital initiatives, marketed products and expansion.

Income Taxes: Income tax benefit for the second quarter of 2023 was \$369 million, driven by the Company's full-year outlook, which includes research and development credits, international provisions, and non-recurring items.

Net (Loss) Income: Net loss was \$(1.4) billion for the second quarter of 2023, compared to net income of \$2.2 billion for the second quarter of 2022.

(Loss) Earnings Per Share: Diluted loss per share was \$(3.62) for the second quarter of 2023, compared to diluted earnings per share of \$5.24 for the second quarter of 2022.

2023 Commercial Updates

COVID - 19: The Company reported \$0.3 billion in COVID-19 vaccine sales in the second quarter, leading to \$2.1 billion in total vaccine sales for the first half of the year, achieving our expectations for the first half of the year. The Company expects 2023 COVID-19 vaccine sales of \$6 billion to \$8 billion, with approximately \$4 billion from previously announced COVID-19 vaccine Advance Purchase Agreements (APAs) and \$2 billion to \$4 billion in signed and anticipated commercial contracts in the U.S., as well as other markets. The range for product sales is primarily driven by the U.S. fall 2023 COVID-19 market size, which is dependent on vaccination rates and is likely to be 50 to 100 million doses. As a result of recent discussions with country level customers, we now expect approximately \$1 billion of the original \$5 billion in APAs to be deferred to 2024. In the U.S., commercial contracts are signed with national and regional pharmacies, wholesalers and distributors, group purchasing organizations, integrated delivery networks & health systems, U.S. Government entities, employers and other providers, and we continue to work on additional contracts. The Company has finalized a contract with the government of Japan for the provision of vaccines for the 2023 vaccination season and is in active supply discussions for additional new orders for fall 2023 in the U.S., EU and other markets.

RSV: The Company continues to expect a 2024 launch of its RSV vaccine with a potential best-in-class profile and has initiated a rolling submission process for a Biologics License Application (BLA) with the FDA. The Company has also completed regulatory applications in Europe, Switzerland, Australia and the U.K., and has started to manufacture mRNA-1345. mRNA-1345 will be provided to customers in ready-to-use pre-filled syringes.

2023 Financial Framework

Product Sales: The Company is expecting 2023 COVID-19 sales of \$6 billion to \$8 billion, dependent on U.S. vaccination rates. Total expected 2023 sales are comprised of approximately \$4 billion from existing APAs and \$2 billion to \$4 billion from additional sales to the U.S., Japan, EU and other countries. Sales will be subject to the timing of regulatory approvals, with the Company currently expecting a 2023 second half sales split of approximately 30% in the third quarter and 70% in the fourth quarter.

Cost of Sales: The Company now expects cost of sales to be approximately \$3.5 billion to \$4 billion for the year.

Research and Development and Selling, General and Administrative 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 approximately \$0.7 billion to \$1.0 billion, driven by an assumed operating loss, R&D credits, international tax provisions and non-recurring items.

Capital Expenditures: The Company continues to expect capital expenditures for 2023 of approximately \$1 billion.

Corporate Updates

Continued Growth:

- Moderna had approximately 5,150 employees as of June 30, 2023, compared to approximately 3,400 employees as of June 30, 2022
- Moderna and IBM **announced** an agreement to explore quantum computing and generative AI for mRNA science
- Moderna **announced** clinical and program updates at its 4th Vaccines Day
- Moderna acquired a site in Marlborough, Mass to support future manufacturing

Company Accolades :

- Moderna was **recognized** as the 6th Most Innovative Company in BCG's annual report (third consecutive year on the list)
- Moderna was **recognized** as #211 on the Fortune 500 (second consecutive year on the list)

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 August 3, 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/Bleed35e9f283f418daaada893c474abbb>

- Webcast: <https://investors.modernatx.com>

The archived webcast will be available on Moderna's website approximately two hours after the conference call and will be available for one year following the call.

About Moderna

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

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product sales	\$ 293	\$ 4,531	\$ 2,121	\$ 10,456
Other revenue 1	51	218	85	359
Total revenue	<u>344</u>	<u>4,749</u>	<u>2,206</u>	<u>10,815</u>
Operating expenses:				
Cost of sales	731	1,381	1,523	2,398
Research and development	1,148	710	2,279	1,264
Selling, general and administrative	<u>332</u>	<u>211</u>	<u>637</u>	<u>479</u>
Total operating expenses	<u>2,211</u>	<u>2,302</u>	<u>4,439</u>	<u>4,141</u>
(Loss) income from operations	(1,867)	2,447	(2,233)	6,674
Interest income	104	40	213	55
				7

Other income (expense), net	14	(13)	(34)	(26)
(Loss) income before income taxes	(1,749)	2,474	(2,054)	6,703
(Benefit from) provision for income taxes	(369)	277	(753)	849
Net (loss) income	<u>\$ (1,380)</u>	<u>\$ 2,197</u>	<u>\$ (1,301)</u>	<u>\$ 5,854</u>

(Loss) earnings per share:

Basic	\$ (3.62)	\$ 5.55	\$ (3.39)	\$ 14.66
Diluted	\$ (3.62)	\$ 5.24	\$ (3.39)	\$ 13.85

Weighted average common shares used in calculation of (loss) earnings per share:

Basic	381	396	383	399
Diluted	381	419	383	423

1 Includes grant revenue and collaboration revenue

MODERNA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in millions)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,801	\$ 3,205
Investments	4,658	6,697
Accounts receivable	232	1,385
Inventory	715	949
Prepaid expenses and other current assets	<u>1,193</u>	<u>1,195</u>
Total current assets	10,599	13,431
Investments, non-current	6,105	8,318
Property, plant and equipment, net	2,280	2,018
Right-of-use assets, operating leases	130	121
Deferred tax assets	1,480	982
Other non-current assets	<u>1,290</u>	<u>988</u>
Total assets	<u>\$ 21,884</u>	<u>\$ 25,858</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 310	\$ 487

Accrued liabilities	1,490	2,101
Deferred revenue	1,040	2,038
Income taxes payable	47	48
Other current liabilities	<u>236</u>	<u>249</u>
Total current liabilities	3,123	4,923
Deferred revenue, non-current	692	673
Operating lease liabilities, non-current	104	92
Financing lease liabilities, non-current	843	912
Other non-current liabilities	<u>173</u>	<u>135</u>
Total liabilities	4,935	6,735
Stockholders' equity:		
Additional paid-in capital	193	1,173
Accumulated other comprehensive loss	(263)	(370)
Retained earnings	<u>17,019</u>	<u>18,320</u>
Total stockholders' equity	<u>16,949</u>	<u>19,123</u>
Total liabilities and stockholders' equity	<u>\$ 21,884</u>	<u>\$ 25,858</u>

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

	<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>
Operating activities		
Net (loss) income	\$ (1,301)	\$ 5,854
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Stock-based compensation	149	94
Depreciation and amortization	170	155
Amortization/accretion of investments	(29)	29
Gain on equity investments, net	(17)	-
Deferred income taxes	(530)	(376)
Other non-cash items	(12)	15
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable	1,153	484
Prepaid expenses and other assets	(142)	(324)
Inventory	234	(480)
Right-of-use assets, operating leases	(9)	20
Accounts payable	(187)	(56)
Accrued liabilities	(633)	305
Deferred revenue	(979)	(2,370)
Income taxes payable	(1)	(527)
	9	

Operating lease liabilities	12	(19)
Other liabilities	<u>(18)</u>	<u>263</u>
Net cash (used in) provided by operating activities	(2,140)	3,067
Investing activities		
Purchases of marketable securities	(1,281)	(8,734)
Proceeds from maturities of marketable securities	3,264	1,409
Proceeds from sales of marketable securities	2,427	2,506
Purchases of property, plant and equipment	(347)	(219)
Acquisition of business, net of cash acquired	(85)	-
Investment in convertible notes and equity securities	<u>(23)</u>	<u>(35)</u>
Net cash provided by (used in) investing activities	3,955	(5,073)
Financing activities		
Proceeds from issuance of common stock through equity plans	25	29
Repurchase of common stock	(1,154)	(1,921)
Changes in financing lease liabilities	<u>(81)</u>	<u>(77)</u>
Net cash used in financing activities	<u>(1,210)</u>	<u>(1,969)</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	605	(3,975)
Cash, cash equivalents and restricted cash, beginning of year	<u>3,217</u>	<u>6,860</u>
Cash, cash equivalents and restricted cash, end of period	<u>\$ 3,822</u>	<u>\$ 2,885</u>

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 submissions to regulators globally for the approval or authorization of mRNA-1273.815; Moderna's ability to supply mRNA-1273.815 in time for the fall 2023 season; anticipated 2023 COVID-19 sales, including the timing of sales, from existing advance purchase agreements and additional sales for delivery in the second half of 2023, which may not be realized; Moderna's discussions for additional new COVID-19 vaccine orders for fall 2023; Moderna's expectations regarding the commercial COVID-19 market, including the U.S. fall 2023 market size, and its ability to effectively compete in such a market; the potential best-in-class profile of Moderna's RSV vaccine, including its efficacy, safety and tolerability profile; the Phase 3 study of Moderna's individualized neoantigen therapy (INT) in adjuvant melanoma; plans to expand INT to additional tumor types, including non-small cell lung cancer; timing for an update from the P303 Phase 3 study; the potential for the enhanced formulation of mRNA-1010 to generate an improved immune response to influenza B strains and to enable licensure of mRNA-1010 through accelerated approval; encouraging early signs of dose-dependent pharmacology and potential clinical benefit for mRNA-3927; Moderna's capital allocation priorities, including anticipated spending on R&D for 2023; Moderna's plans to launch a number of new products in 2024 through 2026, including its RSV vaccine in 2024; and Moderna's 2023 financial framework, including with respect to cost of sales. 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.

Moderna Contacts

Media:

Chris Ridley

Vice President, Communications

617-800-3651

Chris.Ridley@modernatx.com

Investors:

Lavina Talukdar

Senior Vice President & Head of Investor Relations

617-209-5834

Lavina.Talukdar@modernatx.com

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