# First Quarter 2025 Financial Results

May 1, 2025





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Financial figures in this presentation as of, and for the quarterly periods ended, March 31, 2025, and March 31, 2024, are unaudited.



### 1Q25 earnings call agenda



### **Business Review**

Stéphane Bancel, CEO



#### **Financials** Jamey Mock, CFO



#### **Pipeline Programs** Stephen Hoge, M.D., President



#### **Looking Ahead** Stéphane Bancel, CEO

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### **1Q25 financial summary**



Net income (loss) \$(1.0)B

Cash and investments \$8.4B

#### Continuing to execute with financial discipline

Reduced operating expenses by 19% (\$275 million) from 1Q24 to 1Q25<sup>1</sup>

1. Costs including R&D, SG&A and cost of sales

### **Business highlights**



### Expanding markets for our commercial products

- Tender opportunity to compete for COVID vaccine business in the EU
- Recent mRESVIA<sup>®</sup> approvals in Australia, Switzerland, Taiwan and the UK



#### Advancing pipeline to drive sales growth

- Expansion of oncology portfolio, including Checkpoint AIM-T (mRNA-4359)
- Flu vaccine (mRNA-1010) exceeded case accruals required for Phase 3 interim efficacy analysis
- Presented data from RSV, CMV and intismeran autogene (mRNA-4157)<sup>1</sup> at recent medical meetings<sup>2</sup>



## Continuing to execute with financial discipline

 Third consecutive quarter of double-digit year-overyear declines in R&D and SG&A combined

1. Intismeran autogene is the new generic name for mRNA-4157, previously referred to as individualized neoantigen therapy, or INT 2. Please refer to the **"Scientific & Medical Meeting" section** of the Moderna investor website for these presentations



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### First quarter 2025 financial results

In \$ millions, except per share amounts	1	Q 2025	1Q 2024	Change (1Q'25 vs. 1Q'24)	
Net product sales	\$	86	\$ 167	\$ (81)	(49)%
Other revenue <sup>1</sup>		22		 22	100 %
Total revenue		108	167	(59)	(35)%
Cost of sales		90	96	(6)	(6) %
Research and development		856	1,063	(207)	(19) %
Selling, general and administrative		212	274	(62)	(23) %
Total operating expenses		1,158	1,433	(275)	(19)%
Loss from operations		(1,050)	(1,266)	216	(17)%
Other income, net		86	101	(15)	(15) %
Provision for income taxes		7	10	(3)	(30) %
Net loss	\$	(971)	\$ (1,175)	\$ 204	(17)%
Loss per share – Basic and Diluted <sup>2</sup>	\$	(2.52)	\$ (3.07)	\$ 0.55	(18) %
Weighted average shares – Basic and Diluted <sup>2</sup>		386	382	4	1 %
Effective tax rate		(1)%	(1)%		

<sup>1</sup>Includes grant, collaboration, licensing and royalty, and other miscellaneous revenue.

<sup>2</sup>Basic and diluted loss per share were the same as the Company reported a net loss in both periods presented.

In \$ billions	3/31/2025	12/31/2024	Change (3/31 vs. 12/31)		
Cash, cash equivalents and investments	\$ 8.4	\$ 9.5	\$ (1.1)	(12)%	



Total revenue	\$1.5 – \$2.5 billion (1H25: expecting ~\$0.2B reflecting seasonality of the respiratory business)
Cost of sales	~\$1.2 billion
R&D	~\$4.1 billion
SG&A	~\$1.1 billion
Тах	Negligible
Capital expenditures	~\$0.4 billion
Cash and investments	2025 year-end balance of ~\$6 billion



**Financial Review** 

1Q 2025 Update |

### Announcing \$1.4 - \$1.7 billion of cost reductions by 2027



Numbers may not add due to rounding

From 2023 to 2024; costs including R&D, SG&A and cost of sales, excluding resizing charges of \$1.6B for 2023 and \$0.2B for 2024
Depreciation and amortization includes \$0.3B of related manufacturing resizing charges already accounted for in \$1.6B resizing charge and are added back to determine cash costs



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### **Prioritized pipeline**







### **Prioritized pipeline**





### **Respiratory vaccines portfolio**

Respiratory virus vaccines

#### Next-gen COVID mRNA-1283

- Filed in 2024 for approval
- PDUFA May 31, 2025

#### **RSV (18-59 HR)** mRNA-1345

- Filed in 2024 for approval
- PDUFA June 12, 2025

#### Flu + COVID (50+) mRNA-1083

- Filed in 2024 for approval
- Feedback from FDA confirmed need for flu vaccine efficacy data; expect review timeline to be extended; now targeting 2026 approval

#### **Flu** mRNA-1010

• Exceeded case accrual target for Phase 3 vaccine efficacy study in first season; anticipate interim data readout in summer 2025



### Latent + other vaccines and rare disease therapeutics portfolio





1. Please refer to the "Scientific & Medical Meeting" section of the Moderna investor website for these presentations

### **Oncology therapeutics portfolio**

Expanding oncology portfolio with additional intismeran indication and new development candidates

#### Oncology therapeutics

Intismeran autogene mRNA-4157

- Adjuvant melanoma: Phase 3 study fully enrolled
- **NSCLC:** in two adjuvant Phase 3 studies for those with and without prior neoadjuvant treatment
- Adjuvant high-risk muscle invasive bladder cancer: in randomized Phase 2 study
- Adjuvant renal cell carcinoma: in randomized Phase 2 study; fully enrolled
- High-risk non-muscle invasive bladder cancer (HR NMIBC): in randomized Phase 2 study

#### New study

In collaboration with Merck

#### Checkpoint AIM-T mRNA-4359

 First-line melanoma and first-line metastatic NSCLC:
in Phase 2 study

#### **Newly prioritized**

#### Early-stage oncology

#### Tumor-targeted antigen therapy

• <u>mRNA-4106</u>: dosed first patient in Phase 1 study

### Cell therapy-enhancing antigen therapy

• <u>mRNA-4203</u>: IND open



### Checkpoint AIM-T (mRNA-4359) is ongoing in Phase 1/2 study; now enrolling Phase 2 with additional indications planned

#### Immune-targeted antigen therapy



#### Harnessing T-cells with off-theshelf cancer antigen therapies

- Encodes for PD-L1 and IDO
- Targets both immunosuppressive cells and cancer cells



# • **Safety and tolerability** of mRNA-4359 alone and in combination with pembrolizumab

- Antitumor activity of mRNA-4359 alone and in combination with pembrolizumab (ORR, DCR, DOR, PFS)
- T-cell profile changes (peripheral and tumor) after treatment of mRNA-4359 alone or in combination with pembrolizumab

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### **Our execution priorities**

Drive use of Spikevax and mRESVIA vaccines

Focus on 10 product approvals to drive sales growth

Deliver cost efficiency across the business



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### **Our execution priorities**

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### Drive use of Spikevax and mRESVIA vaccines

Entering 2025 with two approved products in the U.S.





Additional approvals for mRESVIA ex-U.S.





### **Our execution priorities**



### Focus on 10 product approvals targeting \$30B+ TAM to drive sales growth



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### **Our execution priorities**





Continue to target cash breakeven in 2028

Numbers may not add due to rounding

1. From 2023 to 2024; costs including R&D, SG&A and cost of sales, excluding resizing charges of \$1.6B for 2023 and \$0.2B for 2024

2. Depreciation and amortization includes \$0.3B of related manufacturing resizing charges already accounted for in \$1.6B resizing charge and are added back to determine cash costs



### **Upcoming catalysts**



- Next-gen COVID (filed, PDUFA date May 31, 2025)
- **RSV 18-59 HR** (filed, PDUFA date June 12, 2025)
- Flu + COVID combo 50+ (filed, targeting 2026 approval)



### Data readouts

- CMV: Phase 3 efficacy
- Seasonal flu: Phase 3 efficacy
- Norovirus: Phase 3 efficacy
- intismeran adjuvant melanoma: Phase 3 efficacy data; Phase 2 5-year durability data
- Checkpoint AIM-T: Phase 1b & Phase 2 data
- **PA:** registrational study efficacy
- MMA: registrational study efficacy



Our mission

# **Deliver** the greatest possible impact to **people** through mRNA **medicines**



# Q&A



# Appendix Moderna's Pipeline



### Moderna's pipeline: Respiratory vaccines

			Preclinical	Phase 1	Phase 2	Phase 3	Commercial	Partner
	COVID-19 vaccine	Spikevax®						
	COVID-19 vaccine Next-gen	mRNA-1283						
	Flu vaccine	mRNA-1010						
A dulta	RSV vaccine older adults	mRESVIA®						
Adults	<b>RSV vaccine</b> 18-59 high risk	mRNA-1345						
	Flu + COVID vaccine	mRNA-1083						
	Pandemic Flu	mRNA-1018						
	RSV + hMPV vaccine	mRNA-1365						
	COVID-19 vaccine adolescents	Spikevax <sup>®</sup>						
Adolescents & Pediatrics	COVID-19 vaccine pediatrics (under EUA)	mRNA-1273						
	RSV vaccine pediatrics	mRNA-1345						



### Moderna's pipeline: Latent + other vaccines

			Preclinical	Phase 1	Phase 2	Phase 3	Commercial	Partner
	CMV vaccine	mRNA-1647						
	<b>EBV vaccine</b> to prevent infectious mononucleosis	mRNA-1189						
	<b>EBV vaccine</b> to prevent or treat long term EBV sequelae	mRNA-1195						
Latent vaccines	HSV vaccine	mRNA-1608						
v de cirres	VZV vaccine	mRNA-1468						
	HIV vaccines	mRNA-1644						
		mRNA-1574						
Enteric	Norovirus vaccines	mRNA-1403						
vaccines		mRNA-1405						
Bacterial		mRNA-1975						
vaccines	Lyme vaccines	mRNA-1982						
Public health vaccines	Zika vaccine	mRNA-1893						
	Nipah vaccine	mRNA-1215						
	Mpox vaccine	mRNA-1769						



### Moderna's pipeline: Oncology

			Preclinical	Phase 1	Phase 2	Phase 3	Commercial	Partner
	Adjuvant melanoma	mRNA-4157						
	Adjuvant NSCLC	mRNA-4157						
Intismeran autogene	Adjuvant NSCLC post neoadjuvant treatment	mRNA-4157						
	RCC	mRNA-4157						
	Bladder cancer (HR MIUC)	mRNA-4157						
	Bladder cancer (HR NMIBC)	mRNA-4157						MERCK
	Early and late solid tumor	mRNA-4157						
Cancer antigen therapies	Checkpoint adaptive immune modulation therapy (AIM-T)	mRNA-4359						
	Solid tumors	mRNA-4106						
	Solid tumors	mRNA-4203						immatics

Abbreviations: NSCLC, non-small cell lung cancer; RCC, renal cell carcinoma; HR MIUC, high-risk muscle-invasive urothelial carcinoma; HR NMIBC, high-risk non-muscle invasive bladder cancer



### Moderna's pipeline: Rare disease therapeutics

			Preclinical	Phase 1	Phase 2	Phase 3	Commercial	Partner
	Propionic acidemia (PA)	mRNA-3927						
	Methylmalonic acidemia (MMA)	mRNA-3705						
Rare disease	Glycogen storage disease type 1a (GSD1a)	mRNA-3745						
therapeutics	Ornithine transcarbamylase deficiency (OTC)	mRNA-3139						
	Crigler-Najjar syndrome type 1 (CN-1)	mRNA-3351						
	Cystic fibrosis (CF)	mRNA-3692 / VX-522						VERTEX

