Case Study: Moderna, Inc.

mRNA Vaccines and Therapeutics

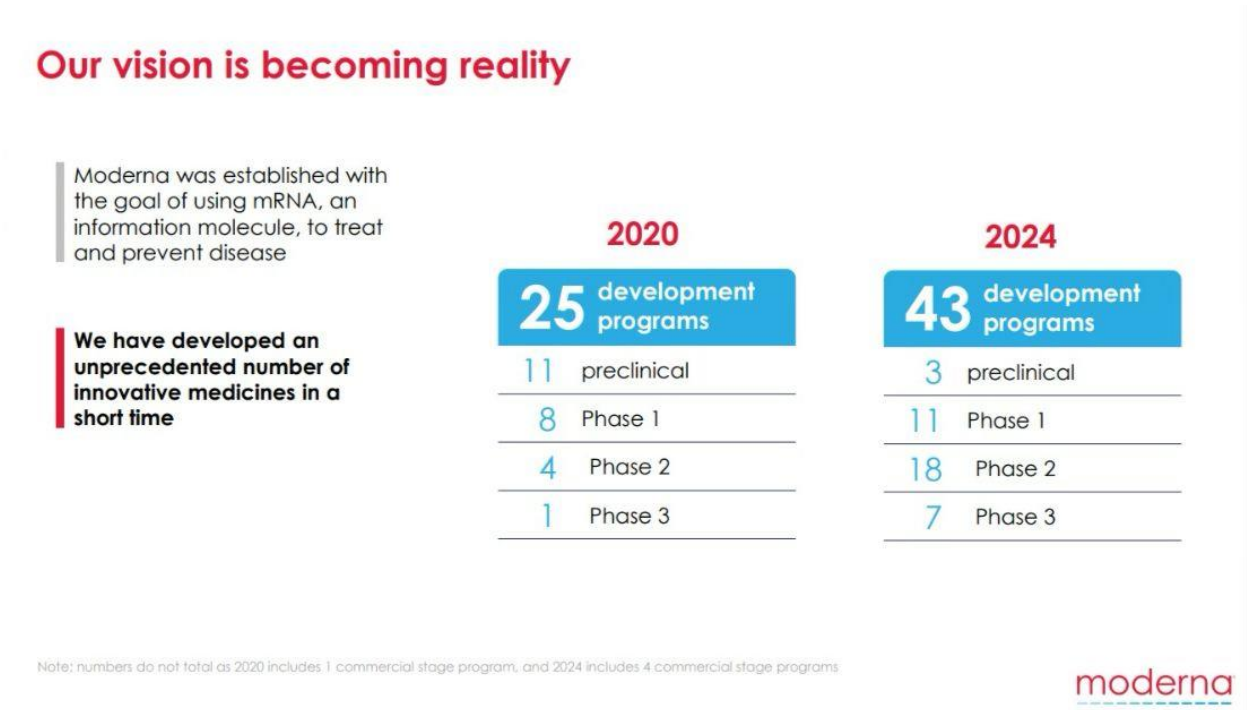
Your Name **Yehya Alaa Trad**

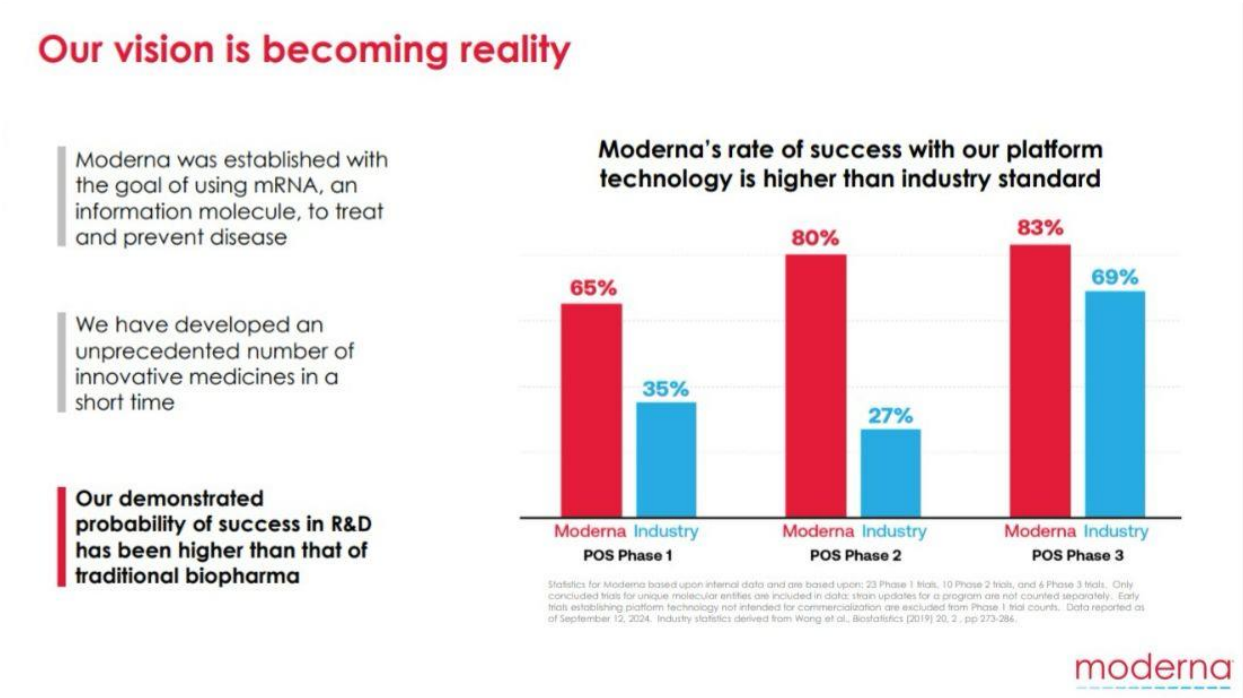
Biotechnology Internship

Moderna, Inc.: mRNA Biotech Case Study

Company Overview

- **Founded:** 2010 in Cambridge, Massachusetts (originally “ModeRNA Therapeutics”). Moderna was co- founded by RNA biologists including Derrick Rossi and is now led by CEO Stéphane Bancel (appointed 2011).
- **Mission:** Specializes in RNA-based therapeutics, primarily messenger RNA (mRNA) vaccines and treatments. Its name “Moderna” derives from “modified RNA” reflecting this focus.
- **Scale:** Publicly traded (Nasdaq: MRNA) biotech with ~5,800 employees (2024). By 2024 it has advanced 44 drug/vaccine candidates (37 in clinical trials) across infectious diseases, rare diseases, and cancer.



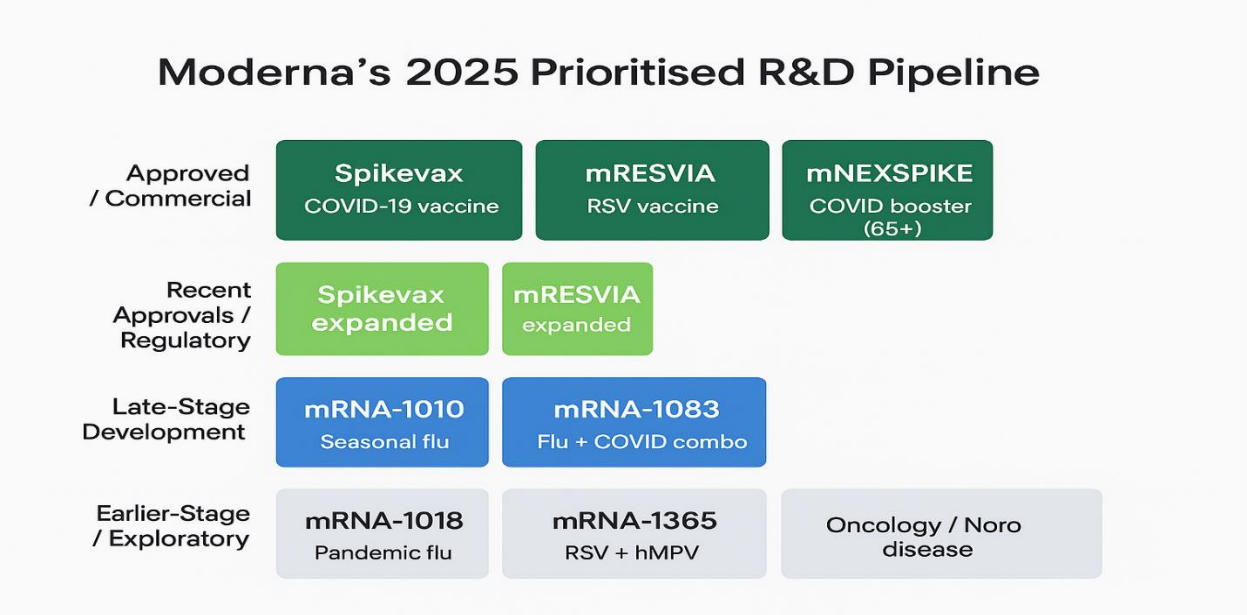


Technology and Innovation

- **mRNA Platform:** Moderna's core innovation is using synthetic mRNA to instruct cells to produce therapeutic proteins. This approach allows rapid design of vaccines by encoding the genetic blueprint of antigens. The COVID-19 pandemic "proved that mRNA was the fastest route to developing highly effective vaccines".
- **Speed & Flexibility:** Moderna demonstrated unprecedented speed: for example, its first human mRNA vaccine trial (an influenza candidate) occurred in 2015. mRNA technology's modularity lets Moderna pivot quickly between targets (COVID, RSV, flu, etc.).
- **Support & Funding:** Moderna secured hundreds of millions in government funding (e.g., DARPA, Operation Warp Speed) to accelerate R&D. For COVID-19, it received nearly $1 billion from U.S. programs, enabling rapid late-stage trials and deployment.

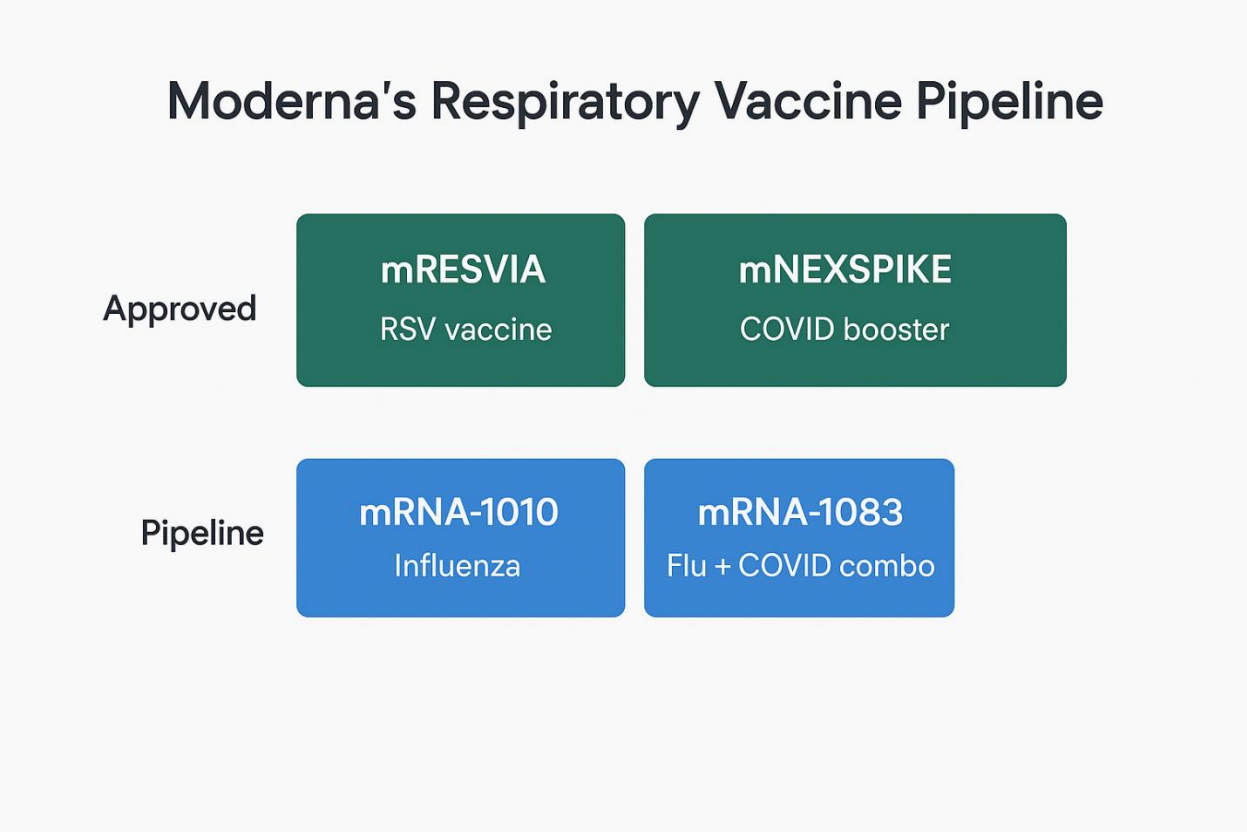
Key Products and Pipeline

- **Spikevax (COVID-19 Vaccine):** Moderna's first approved product, an mRNA vaccine against SARS- CoV- 2. Full FDA approval (as "Spikevax") was granted in early 2022; billions of doses have been administered globally. Spikevax generated most of Moderna's early revenue.
- **mRESVIA (RSV Vaccine):** The company's second approved product (respiratory syncytial virus vaccine for older adults). FDA approval was obtained in 2024. This expanded Moderna's commercial portfolio beyond COVID-19.
- **mNEXSPIKE (New COVID Booster):** Moderna's third product, a 2025-approved variant COVID booster for older/high-risk individuals (65+) and children (6m–11y). This targets waning immunity and viral variants.
- **Pipeline Candidates:** Moderna lists about 44 mRNA vaccine/therapy candidates. These span **infectious diseases** (influenza, cytomegalovirus, Zika, HIV, chikungunya, Nipah, etc.), **cancer vaccines** (e.g. personalized mRNA-4157 for melanoma), and **rare diseases**. The breadth illustrates its platform approach.



Respiratory Vaccines Portfolio

- **COVID-19 Vaccines:** In addition to adult boosters, Moderna has secured authorization for children. Its pediatric Spikevax (for ages 6–11, high-risk) was recently approved[4]. By Fall 2023, Moderna's U.S. market share of COVID-19 vaccines reached ~48% (up from 37% in 2022).
- **mRESVIA (RSV):** Approved for seniors (60+) in 2023, and expanded in 2025 to high-risk adults 18–59[4]. The CDC's Advisory Committee on Immunization Practices (ACIP) has recommended it for these groups, reflecting its public health role.
- **Influenza and Combo Vaccines:** Moderna reported positive Phase-3 results for mRNA-1010 (quadrivalent flu vaccine) demonstrating ~26.6% higher efficacy than standard flu shots[3]. Its flu/COVID combo candidate (mRNA-1083) is in late-stage development. These candidates illustrate efforts to repurpose mRNA tech into routine respiratory vaccines[3].



mRNA-1283 pivotal Phase 3 trial design; sharing vaccine efficacy data today

The Phase 3 was designed to test the immunogenicity, safety and relative vaccine efficacy of mRNA-1283.222 against mRNA-1273.222 in participants 12+ years of age

Design
Randomized 1:1, observer-blind, active-controlled study

Number of participants dosed
11,417 medically stable adults ≥ 12 years old

Vaccination schedule
Single dose of mRNA-1283.222 or mRNA-1273.222
Bivalent vaccine encoding the ancestral and BA.4/5

Duration:
Study participants will be followed up for 12 months after study injection

Site location
US, UK and Canada

Total N=11,417
Randomization Ratio = 1:1

mRNA-1283.222
n = 5,706

mRNA-1273.222
n = 5,711

Spikevax (mRNA-1273): Moderna's Spikevax formulas have been approved/authorized and are available in major markets

Our mRNA platform allowed us to pivot quickly to ensure Spikevax availability for all selected strains

North America

Moderna Receives U.S. FDA Approval for Updated COVID-19 Vaccine Targeting KP.2 Variant of SARS-CoV-2

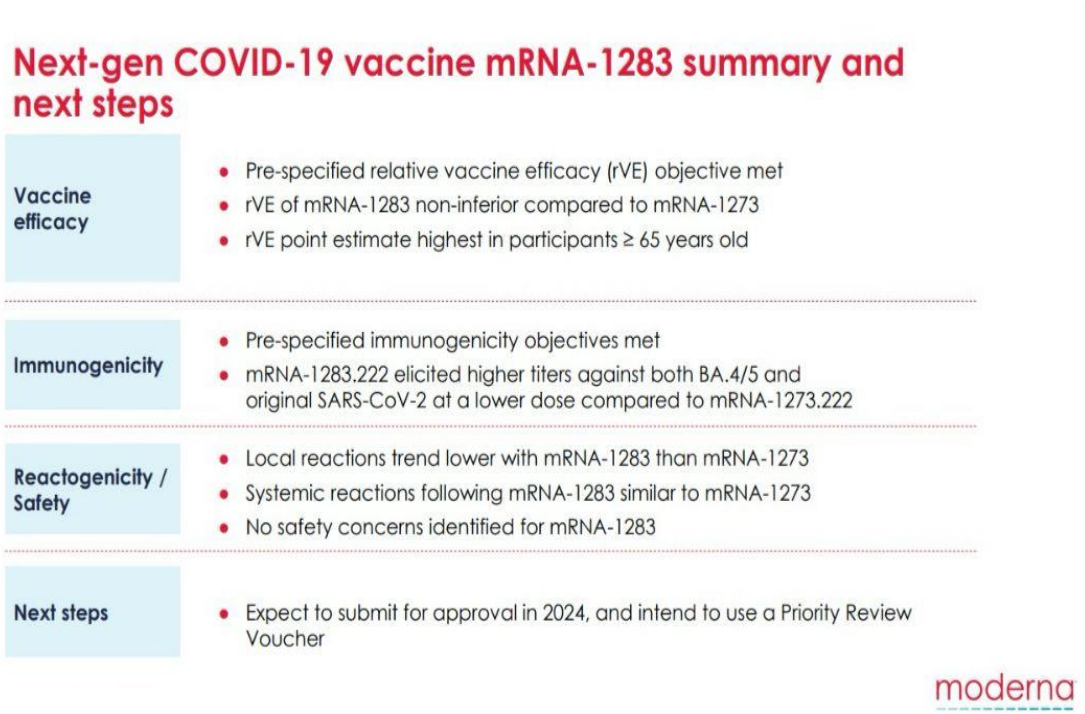
Rest of World

- Taiwan
- Japan
- EU
- UK
- Switzerland
- United Arab Emirates
- South Korea
- Israel

moderna

Market Impact

- **Pandemic Success:** Moderna's mRNA vaccines were central to the COVID-19 response. It delivered hundreds of millions of doses worldwide, demonstrating the real-world power of mRNA. The UK and other governments even partnered to build new mRNA R&D/manufacturing hubs (e.g. Harwell, UK) because of Moderna's success.
- **Revenue Peak:** Sales surged in 2021–2022. Moderna reported roughly **$19.3 billion** in COVID-19 vaccine revenue for 2022, boosting its market capitalization to ~$185 billion at the pandemic peak.
- **Market Share:** In the U.S. retail vaccine market, Moderna's Spikevax achieved about **48%** share in Fall 2023. This was a big gain from 37% in 2022, roughly a 30% relative increase in share over one year.
- **Revenue Decline:** As COVID became endemic, demand fell sharply. By 2024 revenue plunged to around **$3.2 billion**. (This is about an **83%** decline from $19.3B in 2022). Moderna's market capitalization similarly fell ~90% to ~$10 billion by late 2025. These changes reflect the transient nature of pandemic-driven sales.

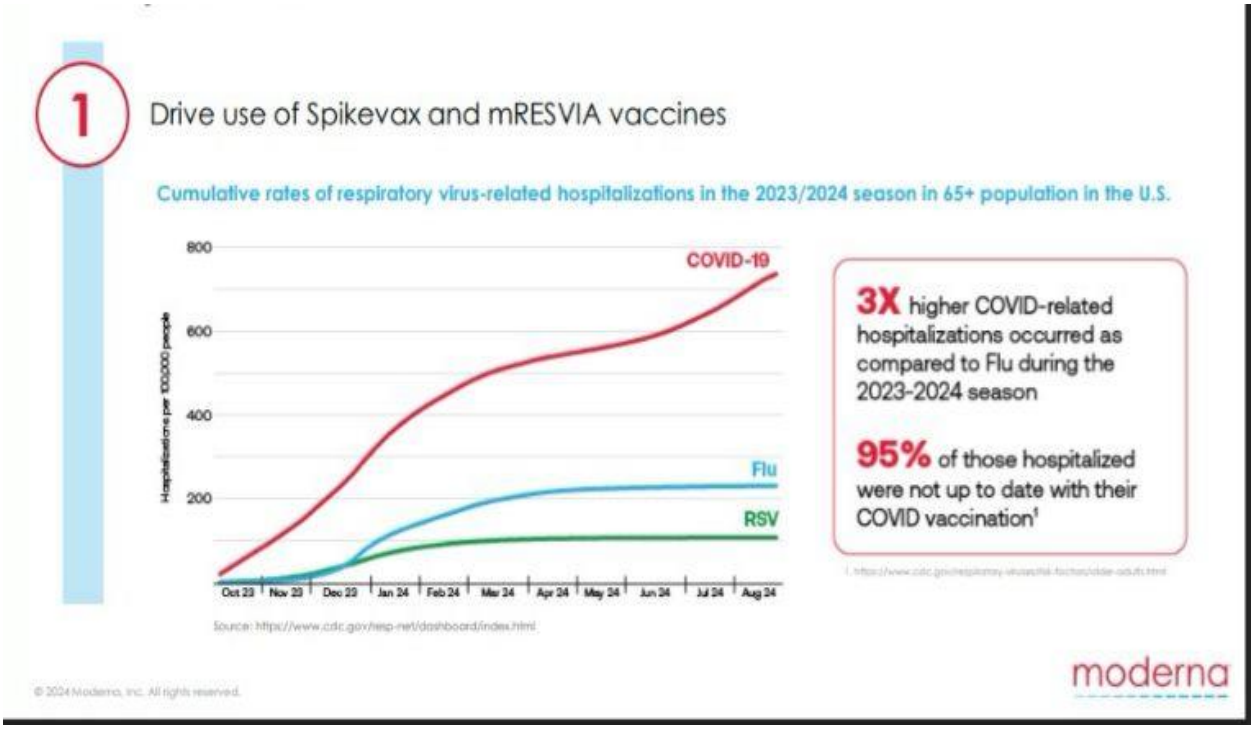


Challenges and Competition

- **Falling Demand:** The swift drop in COVID-vaccine uptake led to massive revenue declines. Moderna has had to slash manufacturing and staffing to align with lower demand, testing its ability to pivot to other products.
- **Government Support:** Originally propelled by Operation Warp Speed, Moderna has faced reduced government buying. In 2025, U.S. HHS canceled a **$766 million** contract for bird-flu vaccine preparedness, indicating policy shifts. (Notably, this occurred under an HHS Secretary known for COVID-vaccine skepticism.)
- **Intellectual Property Battles:** Moderna's mRNA patents are being challenged. For example, in 2025 the U.S. Patent Trial and Appeal Board invalidated key claims of two Moderna COVID-19 vaccine patents following litigation with Pfizer/BioNTech[6]. Ongoing patent disputes introduce risk and uncertainty.
- **Competition:** Other biotech firms (notably Pfizer/BioNTech) also have mRNA vaccines, and new entrants (GSK, CureVac, Sanofi, etc.) are developing mRNA platforms. Success in saturated vaccine markets (influenza, RSV) is not guaranteed.
- **Technical Hurdles:** mRNA drugs require complex manufacturing (lipid nanoparticles, cold-chain). Scaling production efficiently has been challenging; Moderna is addressing this (see below) but it remains a technical barrier.

Financial Performance & Strategy

- **Recent Results:** By 2024 Moderna's annual revenue was about **$3.24 billion**, reflecting the mid-pandemic demand collapse. In Q2 2025, quarterly revenue was **$142 million** (down 41% YoY) with net product sales $114M[7]. The company reported a **net loss of $0.8 billion** for Q2 2025[8].
- **Cost Reduction:** Moderna has aggressively cut costs to improve sustainability. It slashed operating expenses by about 35% in Q2 2025 vs. Q2 2024[8]. Management aims to halve annual operating expenses (from ~$11.1B in 2023 to ~$4.7–5.0B by 2027) to reach breakeven by 2028[9].
- **Cash Reserves:** Despite losses, Moderna maintained a strong cash position (~$7–8B in reserves in 2025[7]), giving it runway to continue R&D and pivot strategies.



Future Outlook and Initiatives

- **New Approvals:** Moderna is expanding its label. As of 2025, it has won FDA approvals for mNEXSPIKE (COVID-19 booster for 65+/high-risk 12–64) and Spikevax for children (6m–11y)[4]. Such expansions should bolster sales in niche segments.
- **Pipeline Progress:** The company is advancing its late-stage programs. For instance, mRNA-1010 (flu vaccine) met its primary endpoint with higher efficacy[3]. It aims to submit these for approval soon. Positive trial results for new vaccines could drive future growth.
- **Cancer Vaccines:** Moderna partners with Merck on mRNA-4157 (a personalized cancer vaccine). This candidate gained FDA “breakthrough” status in 2023. If successful, this could open the lucrative oncology market.
- **Manufacturing & Tech:** To improve production, Moderna acquired OriCiro Genomics in 2023 (creating “Moderna Enzymatics”). OriCiro’s enzyme-based mRNA synthesis can shorten manufacturing times and reduce costs. Moderna also collaborates on advanced tech – for example, partnering with IBM on AI and quantum computing to accelerate R&D.

- **Global Health Partnerships:** Moderna is investing in broader mRNA access. It joined with CEPI (Coalition for Epidemic Preparedness Innovations) to develop outbreak-response vaccines. Its *mRNA Access Program* provides researchers worldwide with mRNA tools for neglected diseases. These initiatives aim to leverage its platform for global health beyond COVID-19.

Conclusion

Moderna has dramatically demonstrated the power of mRNA biotechnology. Its platform enabled one of the world's fastest vaccine developments, saving countless lives in the COVID-19 pandemic. However, this case also shows the volatility of biotech markets: without pandemic demand, revenues plunged by over 80% and the company faces stiff competition and patent uncertainties. Moderna's future hinges on diversifying its mRNA applications – from flu and RSV vaccines to cancer immunotherapies – while executing a leaner operational strategy. Its story highlights how cutting-edge biotech can deliver rapid breakthroughs but must continually innovate and adapt to sustain long-term impact.