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Hearing before the Senate Health, Education, Labor and Pensions Committee

Testimony of Stéphane Bancel
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Chairman Sanders, Ranking Member Cassidy, and distinguished members of the Committee, thank you for the opportunity to appear before you today. My name is Stéphane Bancel, and I am CEO of Moderna, Inc. ("Moderna").

I was born and raised in Marseilles, France, where my formative years were shaped by Jesuit teachings. Jesuit values—the continuous pursuit of excellence, service of the greater good, and social responsibility—have informed my life and leadership of Moderna. I grew up with a keen interest in math, science, and computers, and dreamed of a career in STEM. I first moved to the U.S. in 1994 when I received a need-based scholarship that allowed me to study biochemical engineering in graduate school at the University of Minnesota. I returned to the U.S. in 1998 to go to business school. My experiences as an immigrant and an entrepreneur have taught me the importance of diversity of people and ideas. These values are central at Moderna, where our mission is to deliver the greatest possible impact to people through mRNA medicines.

Moderna is built around the promise of medicines (vaccines or therapeutics) that leverage mRNA technology. Unlike DNA, mRNA molecules move out of a cell's nucleus. Each mRNA molecule contains instructions to produce a specific protein with a distinct function in the body. mRNA thus plays a central role in all biological processes, including in human health and diseases. Our approach fundamentally differs from traditional approaches to medicine; we are a platform company, not a traditional biopharmaceutical company. Rather than introduce a protein or chemical into the body, we send tailored mRNA into cells to instruct them to produce specific proteins. Our mRNA technology is highly adaptable; our platform is uniquely suited to tackle global health's biggest challenges with speed, scale, and flexibility.

We are not a big pharmaceutical company, but we are growing based on these scientific ideas. Since our founding in 2010, we have grown to approximately 4,000 employees globally, including around 3,200 in the U.S. This year alone, we plan to hire 2,000 new employees, around 1,600 of whom will be based in the U.S. To deliver the greatest possible impact to people through mRNA medicines, we are rapidly expanding and investing in people, science, and manufacturing.

Moderna's Beginnings: An American Success Story

While I speak with an accent, I lead a company that is a true American success story.

In 2011, a Moderna co-founder shared preliminary data that showed how mRNA technology could work and asked my opinion. I told him that what he was showing me was not possible, that mRNA could never make human medicines. He then asked what it would mean for medicine if the technology could work. I told him that, if we could get medicinal mRNA technology to work, we could make medicines that had previously been unimaginable. In other words, it would transform the future of healthcare.

I spent weeks debating whether to take the role of Moderna's CEO. My wife asked me what the chances were that Moderna would receive Food and Drug Administration ("FDA") approval for a product. I told her the chance of success was around 5%. But the more I thought about it, the more I became convinced that I had to do it. The technology could, on paper at the time, change medicine forever. It could help treat children with rare genetic diseases for which there was no hope of treatment with traditional pharmaceutical and biotechnology approaches. It could help the millions of people with heart disease and could produce vaccines for infectious diseases. And over time, it could work on many other diseases, maybe even cancer, an illness that has touched my life as it has so many others, perhaps even yours.

So, in 2011, I resigned from my job as CEO of a well-established global company with 6,000 employees and took a significant pay cut to become Moderna's CEO and its second team member. I took a risk on an untested medical technology when the rate of failure in the pharmaceutical industry is around 90%. I knew I had to give the company and the technology my best shot because the consequences for the health of so many people were on the line.

When we started operations in 2011, we only had about $2 million in funding—enough to get us through our first six months. I hired the first few scientists, secured lab and office space, bought machines from a company that had gone bankrupt to save money, and moved us into our office and lab over a weekend. I watched Moderna double in size repeatedly during my first several years on the job. Over the next decade, there were many encouraging signs around the potential of our mRNA platform. But there were many setbacks as well; while we tested several mRNA applications in clinical trials, we were unable to bring a commercial product to market. We lost money every year from our founding until 2021.

Year after year, even when we were losing money, I bought Moderna stock with money my wife and I had saved because I believed in the company. About half of my Moderna shares I purchased as an investor, separate from my CEO compensation. I traveled the world raising money in exchange for shares to keep the dream of mRNA medicines alive.

With support from investors and strategic collaborators, we invested heavily in research and development for our mRNA platform. We built our mRNA platform and funded it through private investment. We took risks and made large investments to

develop our corporate infrastructure, including over $100 million beginning in 2016 to construct our Norwood, MA manufacturing facility. Norwood, an integrated plant capable of full-scale development production, was operational by summer 2018, well before the COVID-19 pandemic.

The early investments we made in our manufacturing capabilities prepared us to rapidly scale our production when the COVID-19 pandemic hit. We did this without support from the federal government and before turning a profit. Over the years, we have partnered with the U.S. government when pressing global health crises have emerged—like Zika and COVID-19—to develop specific medicines enabled by our privately funded mRNA platform.

Clinical Development of our COVID-19 Vaccine

Over Christmas break 2019, I read about an outbreak of pneumonia-like illness in Wuhan, China. I reached out to the U.S. government because I believed our mRNA technology could make a positive impact. In parallel, I directed my team to begin leveraging our proprietary mRNA platform that we had invested in for ten years.

We started working on our vaccine as soon as Chinese scientists posted the virus' genetic sequence online. Our mRNA platform and prior work on coronaviruses enabled us to develop our COVID-19 vaccine in a matter of days. We did all this work before the first case was reported in the U.S. and months before the World Health Organization ("WHO") declared a global pandemic. We did this because we felt a responsibility to do what we could to address the human suffering. Through my prior work on infectious disease outbreaks, I saw how viruses can grow exponentially. I knew every day and every hour mattered in the fight against COVID-19.

On March 11, 2020, the WHO declared COVID-19 a global pandemic. As the world shut down, we continued our work. Each day brought new pressures as we saw case counts and death tolls rise. Our team worked tirelessly, in our homes, lab, and wherever we could. We worked long hours every day, including weekends. My executive team and I worried a lot about how we were going to keep such a pace for a year.

We started Phase 1 clinical trials in March 2020. The first patient received our vaccine in Seattle just 2 months after COVID-19's genetic sequence became available. By way of comparison, this process took 20 months for the SARS vaccine. We were able to move 10 times faster because of our decade of investments in our mRNA platform and our decision years ago to invest in our Norwood manufacturing plant. We received emergency use authorization from the FDA on December 15, 2020. At each step in the process, we were proud to partner with the federal government, through Operation Warp Speed, to answer the call and deliver an effective vaccine.

We worked at an extraordinary pace to bring our vaccine to people as quickly as possible. However, we made sure to slow down when circumstances required. For example, recognizing COVID-19's disproportionate impact on people of color, we slowed enrollment in our Phase 3 clinical trial to ensure diverse representation following discussions with the U.S. government. This effort enrolled 11,000 people of color in our trial, or 37% of our study population. This was a tremendous outcome when you consider that historically, only 6% of all clinical trial participants in the U.S. are people of color. We built a diverse study population to ensure that the outcomes reflected the country's population and to help build public trust in our vaccine.

As our team continued our round-the-clock work on our vaccine, COVID-19 was taking its toll on society. Our hospitals were overrun with sick patients, people were dying alone, and essential workers risked their lives every day to stock food on store shelves and keep us safe. The experiences of our team in those dark days of the pandemic mirrored the rest of the world. We were separated from our families, our children went to school on Zoom, and we suffered the loss of loved ones without being able to say goodbye. Feeling the pain of our fellow citizens gave us the energy and motivation to keep working at an accelerated pace; we knew every hour we worked would get us closer to saving lives. The U.S. government teams also did a remarkable job in those difficult times, and we at Moderna are grateful for their efforts.

Finally, on a Sunday in November 2020 while I was working from home, I received long-awaited news: the results of our Phase 3 clinical trials showed that our vaccine was 94.1% effective at preventing symptomatic COVID-19. When I finished the video conference, I called to my wife and daughters, and we hugged and cried tears of joy and relief. Our accomplishment started to sink in: we had achieved in 10 months what would normally take 10 years. After 10 years of building our mRNA platform, we had developed a tool that would save lives today and change medicine for the future.

Collaboration with BARDA

As outlined in previous sections, we built our mRNA platform and funded it through private investment, including $3.8 billion before the pandemic. We have partnered with the U.S. government when pressing global health crises have emerged—like Zika and COVID-19—to develop specific medicines built from our mRNA technology platform.

The U.S. government gave us $1.7 billion in funding to accelerate clinical trials for our COVID-19 vaccine at the scale and speed it required through grants from the Biomedical Advanced Research and Development Authority ("BARDA"). This was particularly important for us because we are a small company and, unlike big pharmaceutical companies, could not self-fund robust clinical trials.

Grant funding and advance purchase orders from the U.S. government allowed us to accelerate development of our COVID-19 vaccine and enabled us to deliver our

vaccine to the public at a speed we could not have accomplished on our own. We at Moderna, along with the people of this country and the world more broadly, owe the U.S. government a debt of gratitude for its important investment.

We were under no obligation to do so but, recognizing the U.S. government's investment in the later stages, we provided the government a discount versus the other mRNA vaccine. While the government provided $1.7 billion in funding, we returned $2.9 billion.

Innovations like our vaccine can only happen in America. We thank our partners in the federal government for their support and the vote of confidence they cast for our mRNA technology.

Scaling up the Manufacturing of the COVID-19 Vaccines

At the same time, while working through all of the challenges of the clinical trials, we were preparing for manufacturing so that we would be ready to supply quickly in the event that our vaccine was successful in clinical trials. We needed to scale up our manufacturing capacity exponentially. In our ten years of business before the pandemic, we had never produced more than 100,000 product doses per year across our entire pipeline portfolio. By late January 2020, I became convinced that COVID-19 would be a pandemic like the 1918 Spanish Flu. I challenged Moderna's head of manufacturing to come up with a plan to produce a billion doses for distribution in 2021, a daunting 10,000 times more doses than we had produced ever before.

Given the magnitude of the required manufacturing scale-up and the risk of doing so before we knew if our vaccine worked, we solicited outside funding. In May 2020, when our positive Phase 1 clinical trial data went public, our board approved raising $1.3 billion through the capital market (NASDAQ). These private funds raised through the sale of new shares enabled us to hire new employees, buy new equipment and raw materials, set up facilities that met rigorous FDA standards, and establish protocols and processes to keep our employees safe while producing our vaccine in the midst of a global pandemic.

Facilitated by the early investments in our mRNA platform and manufacturing facility, we delivered 300 million doses of our vaccine to the U.S. government in 2021. Our team knew that each dose we produced represented an additional life protected. Vaccines brought relief to our overwhelmed hospital system, put children and teachers back in classrooms, reopened our economy, and made it safe to re-build in-person social networks.

While much progress has been made, it remains a top priority for us to continue supporting efforts to fight COVID-19 and advancing the most efficacious vaccine. To date, our COVID-19 vaccine has been distributed to more than 70 countries and has helped protect the lives of hundreds of millions of people around the world. We

partnered with Gavi's Vaccine Alliance to distribute more than 170 million doses to low- and middle-income countries. However, as demand shifted, Gavi asked to be released from its purchase commitment, which we did. When doses were declined, we recognized write-downs of approximately $1 billion in non-standard costs.[1] Notwithstanding this loss, we have offered Gavi up to 100 million more doses in 2023 at our lowest-tier price.[2]

Our Commitment to Vaccine Access

A lot will change for our company as we step into the shoes of the U.S. government to ensure that everyone who wants a vaccine has access in a convenient location. One thing that will not change is our commitment to delivering the greatest possible impact to people through our mRNA medicines.

We are committed to ensuring anyone who wants a vaccine can get one, without price posing a barrier. Our vaccine will continue to be available at no out-of-pocket cost to insured people. For the uninsured (or underinsured), our free drug program will ensure access by providing COVID-19 vaccines at no cost.

We remain steadfast in our commitment to protecting as many people as possible across the world. To that end, we are building a manufacturing facility in Kenya capable of producing up to 500 million vaccine doses per year. Through this facility we hope to ensure sustainable access to transformative mRNA medicines in Africa and positively impact public health.

Our Approach to Pricing

We are committed to pricing that reflects the impact our vaccine has on patients and healthcare systems. This impact includes lives saved and hospitalizations avoided. The U.S. vaccination program is responsible for an estimated $5 trillion in societal economic value.[3] The Commonwealth Fund estimates that the U.S.

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[1] *See* Moderna 2023 Proxy Statement (March 15, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0001682852/a3589eb3-e49a-4135-a05c-746fe30f466a.pdf.

[2] *See* Moderna Announces Update to 2022 Supply Agreement with Gavi that Secures Access to Updated Variant-Specific COVID-19 Vaccines for Low- and Middle-Income Countries (Oct. 17, 2022), http://investors.modernatx.com/news/news-details/2022/Moderna-Announces-Update-to-2022-Supply-Agreement-with-Gavi-that-Secures-Access-to-Updated-Variant-Specific-COVID-19-Vaccines-for-Low-and-Middle-Income-Countries/.

[3] Noam Kirson et al., The Societal Economic Value of COVID-19 Vaccines in the United States, Journal of Medical Economics (Jan. 20, 2022), https://www.tandfonline.com/doi/pdf/10.1080/13696998.2022.2026118.

vaccination program prevented 18.5 million additional hospitalizations and 3.2 million COVID-19 deaths.[4]

In addition to helping protect the lives of millions of people around the world, our COVID-19 vaccine has also dramatically lessened the pandemic's economic burdens. For example, according to a study published at the end of 2021, COVID-19 vaccines had already saved the U.S. economy approximately $438 billion.[5]

As the pandemic has ended and we move to an endemic phase, the U.S. government will wind down its role as the sole purchaser and distributor of COVID-19 vaccines. We will be offering our vaccine as a commercial product for the first time. Some people may be asking—why does this matter? During the pandemic, we had guaranteed sales to one customer (the U.S. government); moving forward, we are expecting to work with about 10,000 customers. Challenges of endemic distribution include:

- Assuming the cost of producing vaccines that we may not be able to sell given uncertainty in demand for fall of 2023, both in the U.S. and globally;
- Distributing to approximately 60,000 pharmacies, doctors' offices, and hospitals throughout the country, rather than three warehouses;
- Transitioning from 10 dose vials to single dose vials or pre-filled syringes;
- Providing some customers with a "right of return" in which we give them back their money for some purchased product if they can't sell it; and
- Moving from a single 500 million dose contract with the government to a commercial market with demand for perhaps 30–50 million doses, creating more than a 90% volume decrease.

Notwithstanding these challenges, we are committed to a fair price, which will be similar to other vaccines. Notably, our price will be less than two times the cost of enhanced flu vaccines,[6] whereas COVID-19 causes three times as many deaths as the

[4] Meagan C. Fitzpatrick et al., Two Years of U.S. COVID-19 Vaccine Have Prevented Millions of Hospitalizations and Deaths (Dec. 13, 2022), http://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations.

[5] Anusuya Chatterjee et al., Economic Savings in America: A Story of Public-Private Partnership in Rapid COVID-19 Vaccine Development and Deployment, Heartland Forward (Dec. 18, 2021), https://heartlandforward.org/wp-content/uploads/2021/12/Economic-Savings-in-America_7.pdf.

[6] The CVS list price for enhanced flu vaccines is $95. *See* CVS Minute Clinic Price List, available at https://www.cvs.com/minuteclinic/services/price-lists.

flu.[7]

Looking Ahead to the Next Decade and Beyond

We have worked tirelessly to build the industry's leading mRNA platform. We did this while losing money for over ten years so we could make mRNA medicines a reality for the world. This work allowed us to play a leading role in the fight against COVID-19. The success of our COVID-19 vaccine is funding more research to continue transforming the future of medicine, including for cancer and cystic fibrosis.

In 2023, we will invest $4.5 billion in research and development. We are committed to this investment even though analysts expect Moderna to report a loss in 2023. And last year our research and development investment was $3.3 billion—almost 40% of our net revenues, which is about twice the pharmaceutical industry standard.[8] We continue to make these significant research and development investments even as we face declining profits.

Our commitment to broad research and development is illustrated by our development pipeline. We are working to address a wide range of diseases and conditions, including infectious diseases, immuno-oncology, rare diseases, autoimmune diseases, and cardiovascular diseases. We have 48 therapeutic and vaccine candidates in development. We are in dialogue with the WHO and the Coalition for Epidemic Preparedness Innovations ("CEPI") to develop 15 vaccines against priority pathogens that pose a threat to public health. Moderna's clinical portfolio already includes vaccines targeting COVID-19, HIV, Nipah, and Zika. Moderna's expanded global health strategy will advance programs against the remaining pathogens by 2025.

We are working on personalized cancer vaccines, treatments for cystic fibrosis, and a cytomegalovirus ("CMV") vaccine, in addition to the tools to fight future pandemics. Our personalized vaccine for melanoma, a cancer that is expected to kill 8,000 people in the U.S. this year, has the potential to transform outcomes for high-risk resected melanoma patients. Results from a recent Phase 2 clinical trial show that when combined with Merck's KEYTRUDA® cancer drug, our vaccine reduced the risk of cancer recurrence and death by 44%. In partnership with Vertex, we are developing an mRNA therapeutic to treat the underlying cause of cystic fibrosis, a rare genetic disease that causes degeneration of lung function and often death, for which there is no cure. Addressing the root cause of cystic fibrosis with an mRNA medicine could

[7] Sarah Zhang, The 'End' of COVID Is Still Far Worse Than We Imagined, The Atlantic (Sept. 22, 2022), https://www.theatlantic.com/health/archive/2022/09/covid-pandemic-end-worse-than-flu/671514/.

[8] The U.S. government's twenty-year average shows that pharmaceutical companies have invested 19% of their net revenue into research and development. Congressional Budget Office, Research and Development in the Pharmaceutical Industry, at 5 (Apr. 2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.

profoundly improve quality of life for the approximately 5,000 people who live with the disease and do not respond to existing treatments.

For ultrarare diseases—those that impact fewer than 100 people globally—we understand that the cost of therapeutics can put treatment out of reach for many patients. We are committed to considering patient access in our pricing decisions. In the case of Crigler-Najjar Syndrome Type 1 ("CN-1"), rather than commercialize the product, in September 2021, we committed to making the intellectual property available for free through a partnership with the Institute for Lifechanging Medicines at the University of Pennsylvania. Through this partnership, we have committed to providing the medicine for free for pre-clinical and clinical testing. If the medicine receives regulatory approval, we will supply the medicine to families for free forever.

Commitment to Our Community

At Moderna we care deeply—about our patients, our employees, the environment, and our communities. We recognize that we have an opportunity to change medicine for all, and we will continue to make corporate responsibility a critical part of who we are and what we do.

Last year we launched the Moderna Charitable Foundation ("Moderna Foundation" or "the Foundation"). We are proud to extend our social impact and support the causes our employees care most about as we work relentlessly to improve human health with our mRNA technology.

The Moderna Foundation's work reflects our continued commitment to communities impacted by COVID-19. The Foundation provides grants to local and global organizations, makes event-driven philanthropic gifts, and matches employee gifts to certain organizations. Our grant program provides financial support to organizations that focus on healthcare quality and access, mental health, STEM education, food insecurity, and child development.

Conclusion

We at Moderna are grateful for the actions you and your colleagues have taken to support and fund efforts to combat the COVID-19 pandemic. Thank you, and I look forward to your questions.