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9B21M058

MODERNA: IN SEARCH OF A COMPETITIVE EDGE IN THE COVID-19 VACCINE RACE[1]

Saurabh Bhattacharya and Arpita Agnihotri wrote this case solely to provide material for class discussion. The authors do not intend to illustrate either effective or ineffective handling of a managerial situation. The authors may have disguised certain names and other identifying information to protect confidentiality.

Moderna, Inc. (Moderna), headquartered in Cambridge, Massachusetts, was a biotech start-up that had been led by Stéphane Bancel since 2011.[2] It was one of the front-runners in the race to develop a COVID-19 vaccine, with Pfizer Inc. (Pfizer) and AstraZeneca plc (AstraZeneca) among the other active companies in the race (see Exhibit 1). On November 23, 2020, Moderna became the second pharmaceutical company to announce success in third-stage clinical trials of a COVID-19 vaccine (mRNA-1273). Moderna's announcement came immediately after larger rival Pfizer, in partnership with BioNTech SE (BioNTech), had reported the third-stage clinical trial results of its own COVID-19 vaccine (BNT162b2).[3]

Moderna had struggled in the past to find contract manufacturers for the production of its vaccines.[4] For the production of its COVID-19 vaccine, it had strategic partnerships with Switzerland-based Lonza Group AG (Lonza) and Spain-based Laboratorios Farmaceuticos Rovi S.A. (Rovi).[5] Bancel, commenting on Moderna's manufacturing capacity, said that scaling up manufacturing was "going to be bumpy."[6] Moderna required cold storage of the vaccine at −20 degrees Celsius, and it was working on establishing cold storage facilities and a different version of the vaccine that could be stored at a milder temperature.[7] According to the World Health Organization, cold storage logistics were not well developed globally. Every year, a significant amount of vaccines were wasted due to temperature management issues.[8] In addition to the challenges around cold storage, Moderna also had not yet marketed any other vaccine and had never established a medicine distribution channel.[9] On the other hand, Pfizer had its own manufacturing facilities, in Kalamazoo (Michigan) and Puurs (Belgium),[10] and Cambridge, UK-based AstraZeneca had contract manufacturing lined up for development of its COVID-19 vaccine with Asian and European companies.[11] AstraZeneca's vaccine did not require cold storage and could be retained at refrigerated temperatures.[12]

On the consumer front, according to a study by Pew Research Centre by September 2020, 49 percent of Americans were unwilling to be vaccinated for COVID-19 and were protesting vaccination on social media.[13] In November 2020, Moderna was planning to apply for Emergency Use Authorization (EUA) of the COVID-19 vaccine to the US Food and Drug Administration (FDA). Media sources expected FDA officials to meet on December 10, 2020, to discuss Pfizer's COVID-19 vaccine EUA and on December 17, 2020, to discuss Moderna's COVID-19 vaccine EUA.[14]

As vaccine manufacturers were getting into the competition of "My vaccine is better than yours,"[15] could Moderna ultimately win in the race to produce an effective vaccine for COVID-19? Given the uncertainty in consumer demand for a COVID-19 vaccine, should Bancel plan Moderna's manufacturing capability based on end-consumer demand or instead focus on seeking contracts with different countries' governments?

BACKGROUND

Founded in 2010, Moderna had strategic alliances for drug development programs with AstraZeneca and Merck & Co., Inc. apart from several government agencies.[16] The company had been named a top biopharmaceutical employer in the Science and Science Careers' Top Employers Survey for five consecutive years (2015–2019).[17] Moderna launched its initial public offering in December 2018, raising $600 million,[18] and industry experts considered it biotech's largest initial public offering. Since then, its shares had fallen by 34 per cent due to the non-commercialization of any of its medicine or vaccines.[19] Further, by July 2020, heavy investment in Moderna's messenger ribonucleic acid (mRNA) technology had still not made it profitable.[20] However, between January 2020,[21] when Moderna announced its research and development venture into a COVID-19 vaccine, and November 2020, as COVID-19 vaccine development progressed, its share price increased by approximately 800 per cent (see Exhibit 2). In 2020, Moderna had 21 mRNA development candidates (vaccine projects) in its portfolio, with 13 in clinical studies, four of which were on a profit-sharing basis with Merck & Co., Inc.[22]

By July 2020, Moderna had received $955 million in funding for the development of its COVID-19 vaccine from the Biomedical Advanced Research and Development Authority, a division of the Office of the Assistant Secretary for Preparedness and Response within the US Department of Health and Human Services.[23] As Moderna's investment in research and development for COVID-19 vaccine development increased, its net losses also increased compared with 2019[24] (see Exhibit 3). In August 2020, Moderna had 25 employees.[25]

According to Andrew Lo, professor of finance at the MIT Sloan School of Management, vaccines had the highest success rate (40 per cent) among different types of drugs, but very few companies pursued vaccine development.[26] Lo said, "In fact, right now there are only four big pharma companies that are focused on it."[27] He added, "A number of them have left the space, and smaller companies have gone bankrupt or are not developing vaccines anymore." This lack of vaccine development occurred because the returns on vaccine development investments were very low, amounting to a few million dollars.[28] More than 30 companies, ranging from biotech start-ups to large pharmaceuticals, were racing to develop a safe and effective COVID-19 vaccine due to the global crisis resulting from the COVID-19 pandemic.[29] Pharmaceutical companies' key concern was balancing speed with safety, as scientists worried about political influences on vaccine development.[30] The longer pharmaceutical firms tested vaccines before launching them, the greater the probability the vaccines would be safe and effective for humans.[31]

FOCUS ON A COVID-19 VACCINE

To develop a COVID-19 vaccine, both Moderna and Pfizer/BioNTech used mRNA technology (see Exhibits 1 and 4). With this technology, "unlike conventional vaccines, which are produced using weakened forms of the virus, RNA vaccines can be constructed quickly using only the pathogen's genetic code."[32] RNA vaccines worked "by introducing into the body a messenger RNA (mRNA) sequence that contains the genetic instructions for the vaccinated person's own cells to produce the vaccine antigens and generate an immune response."[33] Messenger RNA promised lower vaccine development costs, as it was an easily replicable process. Bancel said, "We call mRNA the software of life."[34] He added, "You can copy and paste the information into a lot of drugs by using the same technology." The implication was that the process for developing the mRNA was similar for all vaccines. Depending on the disease being targeted, scientists needed to alter only the vaccine's genetic sequencing,[35] which they could easily design in a few hours using computers.[36] As scientists used a standardized process to develop mRNA technology-based vaccines, pharmaceutical firms could use the same manufacturing process and facilities to develop different vaccines. Furthermore, Moderna's process used less expensive raw materials (water and enzymes), which also lowered the overall costs.[37]

In 2016, Moderna had failed to develop a vaccine for a Zika virus-related disease. Up until early 2020, Moderna had been working on a vaccine for MERS (Middle East Respiratory Syndrome).[38] When Bancel observed the genetic sequence of the SARS-CoV-2 (COVID-19) virus, which was similar to MERS's genetic sequence, he decided to shift the company's focus toward developing a COVID-19 vaccine.[39] When Bancel pushed for the development of a COVID-19 vaccine, Dr. Stephen Hoge, president of Moderna, expressed concerns. Hoge believed that this focus on the COVID-19 vaccine could jeopardize Moderna's efforts in developing other drugs that had more significant commercialization potential. However, according to Bancel, a COVID-19 vaccine would be a "once-in-a-lifetime opportunity" to save lives.[40] If clinical trials of the vaccine went smoothly, the company could be producing millions of doses, ramping up to what Bancel suggested could be "dozens of millions of doses per month toward next year [2021]."[41] Commenting on the potential of mRNA, Bancel said, "The reason we were able to do the vaccine in 63 days from sequence to injecting the first human is because we have invested more than $2 billion of capital over the last 10 years."[42] While developing an mRNA-based vaccine, Moderna scientists used mRNA to carry a copy of the genetic sequence of the COVID-19 virus (also known as Severe Acute Respiratory Syndrome Coronavirus 2, i.e., SARS-CoV-2) that prompted the human body to produce antibodies to that virus.[43] The mRNA carried the instructions from a person's DNA, telling the cells what to do. Moderna synthesized mRNA with instructions for attacking a disease or pathogen.[44]

Commenting on Moderna's ability to conduct trials a few days after decoding the genome of the COVID-19 virus, Penny Heaton, chief executive officer of the Bill & Melinda Gates Research Institute, said, "It's amazing just how fast we've gotten to this point."[45] She added, "It's like six years of work has been compressed into six months." Some infectious disease experts, such as Paul Offit, chief of the Division of Infectious Diseases at the Children's Hospital of Philadelphia, also expressed concerns about the speed of vaccine development. Citing the example of the Rotavirus vaccine, Offit said the speed with which pharmaceutical companies were working toward developing a COVID-19 vaccine was the very reason for caution. It had taken pharmaceutical companies 25 years to develop a vaccine for the Rotavirus. After the first vaccine attempt, researchers had to further work on the vaccine to remove its side effects.[46]

Until November 2020, no drug approved for human usage had been developed using mRNA technology.[47] In clinical trials, Moderna's COVID-19 vaccine candidate mRNA-1273 was generally safe and well tolerated, and produced immune responses in trial participants.[48] After two doses, the vaccine produced neutralizing virus-fighting antibodies in the human body. These antibodies were four times higher than those found in patients who had recovered from SARS-CoV-2 infections.[49] Vaccine researchers noted that some of Moderna's COVID-19 vaccine volunteers developed neutralizing antibodies while others developed binding antibodies. According to researchers, it was the neutralizing antibodies they were interested in.[50] Moderna's COVID-19 vaccine had caused minor side effects in several patients during the first phase of clinical trials—fatigue, chills, headache, muscle pain, and pain at the injection site.[51]

CHALLENGES FOR MODERNA

Early Challenges

Moderna had in development more than 20 experimental drugs and vaccines for cancer, infectious diseases, and other conditions, but none was close to being commercially available to patients.[52] Historically, it had been difficult for Bancel to recruit top scientists, as Moderna had just $2 million of funding in 2011.[53] In Moderna's early stages, a key concern for industry experts was whether Bancel and his research team could get mRNA, an unstable molecule, into human cells.[54] Moderna had spent several years refining a solution for this process, using microscopic capsules known as lipid nanoparticles to ferry the mRNA into the cells. Once the mRNA was induced, the process by which it created disease-fighting proteins was less

challenging.[55] However, when Moderna developed a flu vaccine during its early years, several contract manufacturing companies had turned down the opportunity to manufacture the vaccine.[56]

COVID-19 Vaccine Challenges

For manufacturing the COVID-19 vaccine, Moderna allied with Lonza, a contract manufacturing company, with the aim of producing 1 billion doses a year.[57] Moderna expected the first batch of the COVID-19 vaccine to be produced by July 2020 at Lonza's US manufacturing facility; the partners would then gauge the situation to determine whether it would be necessary to take on "additional production suites across Lonza's worldwide network," in addition to the manufacturing suites Lonza said it could make available for vaccine production in Switzerland.[58]

In July 2020, the US government decided to monitor Moderna's phase-three clinical trials, and it wanted close monitoring of trial participants.[59] Executives at Moderna resisted the demands of scientific experts to closely monitor changes in trial participants' oxygen levels, which could signal dangerous complications for those who might contract COVID-19.[60] While other pharma companies complied with this close monitoring, Moderna considered the recommendation to be a "hassle" that slowed development. Later, Moderna agreed to some monitoring. Thus, Moderna's launch of phase-three clinical trials was delayed, due to its relative inexperience and its staff's lack of expertise in overseeing the most critical phase of human trials.[61] The US government did not face similar problems with established drug makers, such as AstraZeneca and Johnson & Johnson, who were also working on COVID-19 vaccines.[62] Moderna denied any missteps but acknowledged "differences of opinion" with the US government experts involved in the unprecedented effort to deliver a vaccine within only months. Moderna clarified that its team included people who were experienced in running multiple large-scale trials.[63]

In October 2020, Moderna also signed a contract manufacturing deal with Rovi, which was working on expanding its production line for the COVID-19 vaccine.[64] With this arrangement, Moderna intended to accomplish its goal of manufacturing 1 billion vaccines in 2021.[65] Some contract manufacturers, such as Texas A&M University, mentioned that they could cater to the pharmaceutical orders for traditional antibodies-based vaccines of pharma companies such as AstraZeneca, Sanofi SA, and Novavax, Inc., but they could not manufacture the mRNA technology-based vaccines that Moderna was using.[66] Richard Braatz, a chemical engineering professor at the Massachusetts Institute of Technology, said, "The mRNA approach is the one with the most unknown unknowns."[67]

On November 16, 2020, Moderna announced that its COVID-19 vaccine efficacy was 94.5 per cent.[68] Experts believed it was a game changer, as the vaccine had been developed using the innovative mRNA technology.[69]

THE PFIZER AND BIONTECH ALLIANCE

In March 2020, Pfizer announced it would extend its partnership with BioNTech for the joint development of an mRNA technology-based vaccine to efficiently leverage both companies' expertise and resources.[70] Mikael Dolsten, Pfizer's chief scientific officer and president of worldwide research, development and medical, said,

> We believe that by pairing Pfizer's development, regulatory and commercial capabilities with BioNTech's mRNA vaccine technology and expertise as one of the industry leaders, we are reinforcing our commitment to do everything we can to combat this escalating pandemic, as quickly as possible.[71]

Pfizer was the second-largest pharmaceutical company in the world[72] and offered "medicines, vaccines, medical devices, and consumer healthcare products for oncology, inflammation, cardiovascular, and other therapeutic areas."[73] Pfizer planned to deliver 1.2 billion doses of its COVID-19 vaccine by the end of 2021.[74] Although Pfizer had been a later entrant in the COVID-19 vaccine development race, it was the first to apply to the FDA for an emergency COVID-19 vaccine release.[75]

BioNTech was a company based in Germany that provided biotechnological solutions such as treating tumours in cancer patients.[76] Apart from Pfizer, BioNTech worked with multiple global pharmaceutical collaborators, including Eli Lilly, Genmab, Sanofi, Bayer Animal Health, Genentech, Genevant, and Fosun.[77]

THE ASTRAZENECA VACCINE

AstraZeneca, based in Cambridge in the United Kingdom, was working with Oxford University toward a COVID-19 vaccine, though it was doing so through the traditional vaccine technology.[78] Its vaccine used

> a replication-deficient chimpanzee viral vector based on a weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees and contains the genetic material of the SARS-CoV-2 virus spike protein. After vaccination, the surface spike protein is produced, priming the immune system to attack the SARS-CoV-2 virus if it later infects the body.[79]

This modified cold virus stimulated "both antibodies as well as high levels of killer T-cells, a type of white blood cell that helped the immune system destroy infection."[80] Oxford University's Jenner Institute started a clinical trial of the vaccine in April 2020 with 1,100 people.[81] According to Kate Bingham, the UK government's Vaccine Taskforce chair, the leader of the AstraZeneca–Oxford University COVID-19 vaccine, Sarah Gilbert, had "leapfrogged other vaccine contenders to the point where it will likely finish vaccinating subjects in its big 10,000-person efficacy trial before other candidates even start testing on that scale."[82] Virus experts, including Dr. Anthony S. Fauci, cautioned about AstraZeneca–Oxford University's approach, with Fauci saying, "You've got to be careful if you're temporarily leading the way [versus] having a vaccine that's actually going to work."[83]

Between June and July 2020, all three companies—Moderna, Pfizer, and AstraZeneca—entered into phase-three clinical trials. The likelihood of success for a drug moving from phase one of clinical trials to phase two was about 63 per cent, while the metric was sharply lower, at 31 per cent, for progression from phase two to phase three. However, once a company cleared phase three, the drug's chances of reaching the new drug application stage was 58 per cent.[84]

To manufacture and distribute approximately 2 billion doses of its COVID-19 vaccine, AstraZeneca collaborated with the Serum Institute of India Pvt. Ltd., the world's largest vaccine manufacturer.[85] AstraZeneca also signed several supply and manufacturing deals with companies and governments globally.[86] The company announced that it would make vaccines available globally on a non-profit basis; it could thus limit the pricing power of companies such as Moderna, whose share price had increased significantly in 2020 in anticipation of profits from the COVID-19 vaccine.[87] An AstraZeneca spokesperson said, "The vaccine's simple supply chain and our no-profit pledge and commitment to broad, equitable, and timely access means it will be affordable and globally available, supplying hundreds of millions of doses on approval."[88] However, in November 2020, controversy arose related to AstraZeneca's third-stage clinical trial results.[89] According to experts, the issues related to the vaccine dosage given to some clinical trial participants. Also, the company had pooled trial results from two different countries, Britain and Brazil. Experts considered these issues a deviation from the standard practices followed in reporting drug and vaccine trial results.[90]

SUPPLY AGREEMENTS

Moderna and Pfizer each received contracts from the US government to supply 100 million doses.[91] Both companies also received COVID-19 vaccine supply contracts from governments in Canada, United Kingdom, and Japan. In August 2020, Moderna received a supply agreement with the US government for an initial 100 million doses of mRNA-1273, soon followed by an agreement from the Canadian government to supply 20 million doses of mRNA-1273.[92] In October 2020, Moderna signed a contract with the government of Japan to supply 50 million doses of the COVID-19 vaccine.[93] Due to the limited supplies of each vaccine available initially, only 20 million Americans were expected to be vaccinated with Pfizer's COVID-19 vaccine by the end of December 2020.[94] The European Commission negotiated with AstraZeneca on behalf of the 27 European Union (EU) countries and secured a vaccine purchase contract of 300 million dosages with the flexibility of adding another 100 million. Under this alliance, the AstraZeneca vaccine was to be made available to all non-EU countries in Europe.[95] Bancel planned to provide 500 million–1 billion worldwide vaccine doses by the end of 2021,[96] though in 2020 the company expected to supply only 20 million doses.[97]

CHALLENGES DELIVERING COVID-19 VACCINES

According to the World Health Organization, due to cold storage logistics issues, 50 per cent of vaccines were wasted each year.[98] Cold chains in developing countries were so scarce that any vaccine shipment to these countries was a futile effort.[99] The International Air Transport Association, based in Canada, claimed that providing a single dose of the COVID-19 vaccine to 8 billion people, i.e., the world population, would require 8,000 Boeing 747 cargo aircraft, whereas Moderna, Pfizer, and AstraZeneca vaccines required two doses for complete effectiveness.[100] Cold storage of the vaccines added to the global logistics problem, as not all cargo planes were equipped with a low-temperature facility.[101] Experts highlighted that this need for cold storage could make it difficult for two-thirds of the global population to access the COVID-19 vaccine.[102] United Parcel Service began to invest in frozen storage facilities in Louisville, Kentucky, and Venlo, Netherlands, with the storage facility sites exceeding the size of a football field. These two cold storage farms had the potential to store vaccines at −80 degrees Celsius.[103]

Moderna's COVID-19 vaccine required cold storage at a temperature of −20 degrees Celsius,[104] while Pfizer's COVID-19 vaccine required storage at −70 degrees Celsius.[105] The AstraZeneca vaccine required refrigeration at between 2 and 8 degrees Celsius.[106] After thawing, Moderna vaccines could be kept in a refrigerator for 30 days, while the longevity of Pfizer's vaccine after thawing was five days.[107] Moderna's vaccine was durable in regular refrigeration for 30 days because Moderna had mastered the method of strengthening lipid nanoparticles that were the structural backbone of any vaccine.[108] Other techniques to enhance a vaccine's stability included adding inert preservatives to the liquid used to store the concoction, or modifying the nanoparticles' structure to better protect the RNA strand from deterioration in warmer temperatures.[109] Some vaccines, such as those for measles and yellow fever, were shipped in a freeze-dried format and were reconstituted with water before they were administered. Experts were of the view that something similar was possible for COVID-19 vaccines.[110] Juan Andres, chief technical operations and quality officer at Moderna, commented on the cold storage issue:

> We believe that our investments in mRNA delivery technology and manufacturing process development will allow us to store and ship our COVID-19 vaccine candidate at temperatures commonly found in readily available pharmaceutical freezers and refrigerators. This was because storage in normal refrigerators for up to 30 days after thawing enabled normal distribution and flexibility to make wider-scale vaccination possible in the United States and other parts of the world.[111]

However, after the struggles the United States had experienced regarding adequate supply chains for COVID-19 tests, masks, and personal protective equipment, experts were concerned that the same issues could arise in supplying vaccines.[112] Caesar Djavaherian, an emergency room physician and the chief clinical innovation officer at Carbon Health, said, "There's almost an assumption that once a vaccine is created and approved, then everyone is healthy and fine, but the operational component is pretty complex."[113] He added, "We've never tried to administer vaccines to 100 million Americans in a short period of time." According to media sources, several aspects of COVID-19 vaccine transportation were susceptible to risks. For example, bad weather could delay delivery flights; freezers on refrigerator trucks could fail; vaccine shipping containers could remain stuck on the tarmac; coolers could leak; every time a freezer was opened to move things in and out the stored vaccines could be harmed; or every breach in temperature control could potentially degrade the vaccine's efficacy.[114]

Pfizer's vaccine shipping system could hold up to 5,000 doses of its vaccine at the requisite temperature of −70 degrees Celsius for 10 days, as Pfizer intended to ship using dry ice.[115] Pfizer was also spending more than $2 billion to develop its distribution network so that shipping of its vaccine containers would be on a just-in-time basis to the places that needed vaccines, to bypass the need for warehouses.[116] Although this strategy could help regional clinics and small hospitals avoid the need for storage facilities, the availability of the required large amounts of dry ice remained a challenge.[117] Pfizer was also working on a chemical formula that could sustain the vaccine at a less cool temperature. Aliasger Salem, chair of pharmaceutical sciences at the University of Iowa, said, "They're [Pfizer is] working on a powder version that would have even less cold requirements, but it's a work in progress."[118] A spokesperson for Pfizer also mentioned that it was expecting to release a different COVID-19 vaccine in 2022 that could be stored at between 2 and 8 degrees Celsius.[119] Although AstraZeneca required a chilled (rather than frozen) supply chain, according to sources, maintaining a proper chilled chain was also very sophisticated, similar to frozen vaccines.[120]

THE CONSUMER RESPONSE TO COVID-19 VACCINES

According to doctors and epidemiologists, "herd immunity" would be difficult to reach, as it required 70 per cent of the population to be vaccinated.[121] Nevertheless, in an August 2020 survey by Gallup, Inc., 35 per cent of Americans said they would prefer not to be vaccinated even if it was free.[122] A September 2020 study conducted by the Pew Research Center found that almost half of participants would not get vaccinated if a vaccine were available to them at the time the study was conducted (see Exhibit 5). Moreover, historically, some individuals not in favour of vaccines would spread rumours about a vaccine. For example, when a vaccine for mumps was launched, anti-vaccine individuals spread misinformation that the mumps vaccine could lead to autism, causing an overall decline in demand for vaccines.[123] In terms of COVID-19 vaccines, anti-vaccine individuals were misinforming others on social media, stating that the vaccine contained monkey brains or that it was a Central Intelligence Agency plot to take over the world.[124] The record speed at which companies were developing COVID-19 vaccines was a genuine concern among people, as it questioned such vaccines' safety.[125]

The US government was expected to respond to misinformation about COVID-19 vaccines through public education campaigns. Dr. Francis Collins, director of the National Institutes of Health, stated, "We haven't done a good job of getting [coronavirus vaccine] information out there. Speaking for myself, I think I underestimated the level of public resistance," adding, "I didn't expect it to be that widespread."[126] Michael Caputo, an assistant secretary for the US Department of Health and Human Services, said, "We see more vaccine hesitancy with the COVID-19 vaccine than with other vaccines. We know that. This concerns us, of course."[127] A spokesman for "Operation Warp Speed" assured the public that a public education campaign would "soon focus" on vaccine education. Operation Warp Speed was the US President Donald Trump administration's "national program to accelerate the development, manufacturing, and distribution

of COVID-19 vaccines, therapeutics, and diagnostics (medical countermeasures)."[128] Chelsea Clinton, who did vaccine advocacy work with the Clinton Foundation, commented that the "power of the anti-vaccine movement should not be underestimated."[129] In 2019, the anti-vaccine movement was very prolific on social media for the measles vaccine. Clinton remarked, "Unfortunately, the anti-vax content is much more viral, much stickier than the pro-vaccine, pro-public health, pro-science content."

In the past, the United States had mandated vaccines unless they should be avoided for religious or philosophical reasons. In 1901, Cambridge, Massachusetts, mandated the smallpox vaccine for all individuals above 21 years of age, with a fine of what was equivalent to $150 in 2020 for those who failed to follow the mandate. In the United States, the last smallpox outbreak occurred in 1949.[130] Legally, employers in any industry in the United States could compel their employees to be vaccinated against COVID-19.[131] Even consumers could be mandated to show COVID-19 vaccine certification to visit any public place, including restaurants and shopping malls.[132]

THE ROAD AHEAD

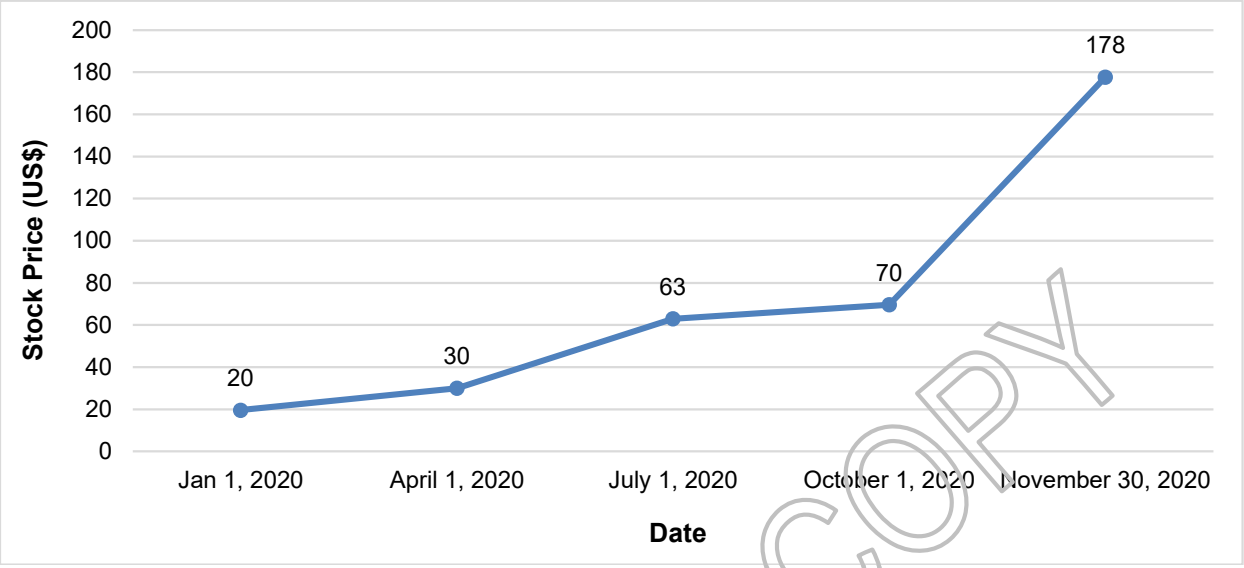
Bancel had consistently cast his company's mRNA technology, which he called the "software of life," as a breakthrough in the vaccine development's speed and effectiveness. He said, "We are not aware of anybody else who can do this at this scale, with this focus, at this speed."[133] According to Peter Pitts, former FDA associate commissioner and president of the Center for Medicine in the Public Interest, a New York-based research and educational organization, in the development of a vaccine, "Often the higher the boasting, the lower the chance of actual success."[134] Regulators and a company determined a vaccine's actual efficacy after all the evaluation of all volunteers in a clinical trial. Generally, regulators and companies considered a vaccine effective if it had an efficacy of 60 per cent or above—and efficacy above 90 per cent was entirely unheard of, though companies such as Moderna and Pfizer had made these claims, based on a very small sample.[135] Maria Bottazzi, co-director of the Texas Children's Hospital Center for Vaccine Development in Houston, said about the efficacy of several COVID-19 vaccines, "Let's wait until the final data."[136] She added, "Let's also wait to see the peer-reviewed publication that will highlight the science behind the press releases." According to media reports, it was too early to declare a winner in the COVID-19 vaccine race, as it was unknown how the vaccines would perform on population demographics at large.[137] What could Moderna do to gain a competitive edge over other leading pharmaceutical companies?

EXHIBIT 1: LEADING COVID-19 VACCINE CANDIDATES

Company (Vaccine Name)	Vaccine Technology	Trial Size	Dosages	Temperature (Degrees Celsius)	Trial Start	Trial Results	Efficacy	Price per Dose (US$)
Pfizer–BioNTech (BNT162b2)	mRNA	44,000	2	−70	April 29, 2020	November 9, 2020	95%	19.50
Moderna (mRNA-1273)	mRNA	30,000	2	−20	July 27, 2020	November 16, 2020	95.10%	25.00
AstraZeneca–Oxford (ChAdOx1 nCoV-2019)	Genetic material from the coronavirus with a modified adenovirus	65,000	2	2 to 8	August 28, 2020	November 23, 2020	70%	3.00
Novavax (NVX-CoV2373)	Purified pieces of the spike protein of SARS-CoV-2	45,000	2	2 to 8	September 28, 2020			16.00
Johnson & Johnson (JNJ-78436735)	Genetic material from the coronavirus with a modified adenovirus	70,000	1	2 to 8	September 27, 2020			10.00

Note: mRNA = messenger ribonucleic acid.
Source: "U.S. Approves First Coronavirus Vaccine to End the Pandemic," Bloomberg, December 12, 2020, accessed December 12, 2020, www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/; Katie Jennings, "How Much Will a Covid-19 Vaccine Cost?," *Forbes,* November 17, 2020, accessed December 10, 2020, www.forbes.com/sites/katiejennings/2020/11/17/how-much-will-a-covid-19-vaccine-cost/?sh=6078a985576d; Peter Beaumont, "Oxford AstraZeneca Vaccine to Be Sold to Developing Countries at Cost Price," *Guardian*, November 23, 2020, accessed December 10, 2020, www.theguardian.com/global-development/2020/nov/23/oxford-astrazeneca-results-covid-vaccine-developing-countries; Sissi Cao, "Here's How Much COVID-19 Vaccines Will Cost from the 5 Frontrunners," *Observer,* August 5, 2020, accessed December 10, 2020, https://observer.com/2020/08/covid19-vaccine-price-comparison-moderna-pfizer-novavax-johnson-astrazeneca/.

EXHIBIT 2: MODERNA SHARE PRICE (JANUARY TO NOVEMBER 2020) (US$)



Source: "Moderna, Inc. (MRNA): NasdaqGS - NasdaqGS Real Time Price," Yahoo Finance, December 10, 2020, accessed December 10, 2020, https://finance.yahoo.com/quote/MRNA/history?period1=1575908104&period2=1607530504&interval=1mo&filter=history&frequency=1mo&includeAdjustedClose=true.

EXHIBIT 3: MODERNA FINANCIALS (NINE MONTHS ENDING SEPTEMBER 30), 2019–2020 (IN US$ MILLION)

		2019	2020
Revenue:			
	Grant revenue	8.7	187.5
	Collaboration revenue	37.5	45.1
Total revenue		46.2	232.7
Operating expenses:			
	Research and development	378.4	611.5
	General and administrative	83.9	109.3
Total operating expenses		462.3	720.8
Loss from operations		−416.1	−488.1
Interest income		30.5	20.5
Other expense, net		−5.7	−5.9
Loss before income taxes		−391.3	−473.5
Provision for (benefit from) income taxes		−0.5	1.1
Net loss		−390.7	−474.6

Source: US Security and Exchange Commission, "Moderna Reports Third Quarter 2020 Financial Results and Provides Business Updates," October 29, 2020, accessed December 10, 2020, www.sec.gov/Archives/edgar/data/1682852/000119312520280422/d134701dex991.htm.

EXHIBIT 4: TRADITIONAL VERSUS MRNA VACCINES

	Traditional Vaccine	mRNA vaccine
Time	10–15 years	4–7 years
Component	Inactive microbe	Blueprint of protein
Process development	Customized for each vaccine	Largely standardized
Process nature	Components made in a lab and injected in the arm so that immune response is stimulated	Components are injected in the arm that instruct the body to make microbial protein
Production	Slower and challenging to produce the right amount of inactive protein	Faster, as mRNA is easier to produce
Potency	Adjuvant sometimes needs to be given to trigger acquired immune response	No need for adjuvant, as it triggers the innate immune system
Facility scalability	Customized for each vaccine	Standardized
Cost	$200 million–$1 billion	$100 million–$200 million
Stockpiling	High volume of finished product that requires replenishment	Stockpiling of finished product not required; can be manufactured in low volume
Reliability of technology	Several vaccines produced using the traditional way	An innovative approach, no drug approved so far

Note: mRNA = messenger ribonucleic acid; All currency amounts are in US$
Source: Joanna Roberts, "Five Things You Need to Know About: mRNA Vaccines," *Horizon,* April 1, 2020, accessed December 10, 2020, https://horizon-magazine.eu/article/five-things-you-need-know-about-mrna-vaccines.html; Sanjay Mishra, "How mRNA Vaccines from Pfizer and Moderna Work, Why They're a Breakthrough and Why They Need to Be Kept So Cold," *The Conversation,* November 18, 2020, accessed December 10, 2020, https://theconversation.com/how-mrna-vaccines-from-pfizer-and-moderna-work-why-theyre-a-breakthrough-and-why-they-need-to-be-kept-so-cold-150238; Evan Rachlin and Michael Watson, "mRNA Vaccines: Disruptive Innovation in Vaccination (White Paper)," Moderna, May 2017, accessed December 10, 2020, www.modernatx.com/sites/default/files/RNA_Vaccines_White_Paper_Moderna_050317_v8_4.pdf.

EXHIBIT 5: PERCENTAGE OF AMERICANS WHO WOULD GET OR WOULD NOT GET THE COVID-19 VACCINE (MAY AND SEPTEMBER 2020)

	Item	Demography/Item	May (%)	September (%)
Total	**Would get the vaccine**		72	51
	Would not get the vaccine		27	49
Gender	**Would get the vaccine**	Male	76	56
		Female	69	45
Age (in years)	**Would get the vaccine**	18–29	68	56
		30–49	67	46
		50–64	72	48
		65 and older	84	58
Would not get the vaccine (Major reason)		Concerned about the side effects		76
		Want to know more about how well it works		72
		Do not think they need it		31
		It would cost too much		13

Source: Alec Tyson, Courtney Johnson, and Cary Funk, "U.S. Public Now Divided over Whether to Get COVID-19 Vaccine," Pew Research Center, September 17, 2020, accessed December 10, 2020, www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/.

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