



Coronavirus update: Pharma companies of all sizes working toward vaccines

From Big Pharma down to small startups, many pharmaceutical companies are currently developing vaccines for COVID-19. Since the virus first appeared in December, some 7.3 million people worldwide have been infected with the new coronavirus, and more than 411,000 have died, according to numbers released in mid-June. No drugs or vaccines have yet received FDA approval.

In the United States, many of the publicly traded companies that have begun vaccine development have received funding from two organizations: the Biomedical Advanced Research and Development Authority (BARDA), which is a division of the Department of Health and Human Services; and the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health. Some companies have also received funding from Coalition for Epidemic Preparedness Innovations (CEPI), a global organization based in Oslo, Norway that has provided millions of dollars in funding to vaccine makers. Other companies are funding trials independently or through partnerships with life-sciences companies. The following companies were developing vaccines in United States as of May.



Altimune

Type: Vaccine
Stage: Preclinical
Name: AdCOVID

Background: Altimune said March 30 it was partnering with University of Alabama at Birmingham to develop a single-dose, intranasal COVID-19 vaccine. They said they plan to put the vaccine candidate into phase 1 trials in the third quarter of 2020. The preclinical company is also developing vaccines for anthrax and the flu.

Year-to-date stock performance: Shares of Altimune have gone up 60.8%.

BioNTech and Pfizer

Type: mRNA vaccine
Stage: Phase 1/2
Name: BNT162 program
Investment made: \$185 million

Background: Pfizer announced March 17 it would help develop and distribute BioNTech SE's COVID-19 vaccine candidate, though the deal excludes China. The 360 patients in the U.S. trial had started to receive the first doses of the four vaccine candidates included in the study as of May 5. Dosing in 200 participants in the German trial began April 23. As part of the deal, Pfizer will pay \$185

million upfront, with additional possible future milestone payments of as much as \$563 million. Mikael Dolsten, Pfizer's chief scientific officer, said during an April 28 earnings call that the companies expect the first round of trial data in May or June, with the vaccine candidate moving into "expanded trials that could allow emergency use or accelerated approval coming in the fall, possibly October." BioNTech is also testing the vaccine in collaboration with Shanghai Fosun Pharmaceutical Group in China. Pfizer and BioNTech have said for several years they are working on mRNA-based influenza vaccines.

Year-to-date stock performances: Shares of BioNTech have soared 47.6%; Pfizer's stock is down 1.7%.



GlaxoSmithKline

Type: Vaccine, treatment

Name: AS03 adjuvant system for vaccines

Background: GlaxoSmithKline is another leading vaccine maker, having brought to market vaccines for human papillomavirus (HPV) and the seasonal flu, among others. It has announced a string of wide-reaching collaborations during the pandemic, most notably a deal with Sanofi to jointly develop a vaccine candidate (Sanofi is also working with BARDA on a separate vaccine program). As part of this agreement, Sanofi's S-protein COVID-19 antigen will be paired with GlaxoSmithKline's adjuvant technology; the companies expect to launch clinical trials in the second half of the year. Terms of the agreement are expected to be completed this month.

Other projects: GSK said on February 3 that the CEPI-funded University of Queensland will have access to its vaccine adjuvant platform technology, which is believed to both strengthen the response of a vaccine and limit the amount of vaccine needed per dose. A separate deal with Clover Biopharmaceuticals Inc., a Chinese biotechnology company, which was announced in February, is also using its adjuvant technology in combination with its vaccine candidate, COVID-19 S-Trimer, in preclinical studies. Dr. Thomas Breuer, chief medical officer for GSK Vaccines, is leading work on vaccines and the adjuvant platform.

Separately, GSK and Vir Biotechnology announced a deal in early April, in which GSK made a \$250 million equity investment in Vir as the two companies work together to develop two of Vir's experimental therapies, VIR-7831 and VIR-7832, expected to go to phase 2 clinical trials sometime in 2020.

Year-to-date stock performance: Shares of GSK have tumbled 11.3%.



Heat Biologics

Type: Vaccine

Stage: Preclinical

Background: Heat Biologics has previously announced that it is developing a vaccine for the novel coronavirus with the University of Miami Miller School of Medicine. It disclosed March 17 in a financial filing that its COVID-19 vaccine candidate had been added to the World Health Organization's "draft landscape" of 41 candidate vaccines. "We are finalizing completion of the vaccine and plan to commence preclinical testing this quarter," Heat CEO Jeff Wolf said in an April 29 statement.

The company also recently joined the Alliance for Biosecurity, which may help it "secure government funding to support its rapid development, production, and distribution" of its COVID-19 vaccine, according to Maxim Group analysts.

Year-to-date stock performance: Heat's stock has gained 14.8%.



Inovio Pharmaceuticals

Type: DNA-based vaccine

Timeline: Phase 1 clinical trial

Name: INO-4800

Investment made: \$17 million (by CEPI)

Background: Another CEPI grantee (with roughly \$17 million in total awards), Inovio Pharmaceuticals is testing its vaccine candidate in a phase 1 clinical trial at two sites in the U.S.: the Perelman School of Medicine at the University of Pennsylvania and the Center for Pharmaceutical Research in Kansas City, Mo.

Inovio develops immunotherapies and vaccines but hasn't yet had a product approved for treatment. For INO-4800, preclinical testing was performed between January 23 and February 29. The company began clinical trials in the U.S. with as many as 40 participants in April, dosing the first patient on April 6. Inovio said it expects to have the first results from the trial in the fall and to have 1 million doses of the vaccine ready for addition-

al clinical trials or emergency use by the end of the year. On March 12, Inovio announced a \$5 million grant from the Bill & Melinda Gates Foundation to test a delivery device for its vaccine candidate. In late March, Inovio said that Ology Bioservices, a contract development and manufacturing organization, had received a \$11.9 million contract from the Department of Defense to support future potential manufacturing of Inovio's vaccine candidate for military personnel.

Year-to-date stock performance: Shares of Inovio have soared 209.5%.



Johnson & Johnson

Type: Vaccine

Stage: Preclinical

Investment made: \$1 billion each by J&J and BARDA

Background: Johnson & Johnson (J&J) announced February 11 that it was working with BARDA to test its vaccine candidate, with each party providing \$1 billion for research and development and the public-health organization funding the phase 1 trials.

"We are also in discussions with other partners, that if we have a vaccine candidate with potential, we aim to make it accessible to China and other parts of the world," Dr. Paul Stoffels, J&J's chief scientific officer, said in a statement.

On March 13, J&J said it started preclinical testing on multiple candidates in collaboration with Beth Israel Deaconess Medical Center in Boston, and by March 30 it had identified a lead vaccine candidate. The company said it is scaling up its vaccine manufacturing capabilities in the U.S. and abroad as part of its commitment to bring "an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use."

The company aims to put its lead vaccine candidate in a phase 1 clinical trial in September, the company said March 30, and it may have investigational doses of the vaccine available by early 2021 for emergency use.

Other projects: J&J said in February that it had partnered with BARDA on a project that aims to screen existing antiviral medications, including experimental or approved therapies, that may be effective against COVID-19. Similar to GSK, J&J's AdVac and PER. C6 technologies are used to improve the development process for a vaccine and were also used to develop J&J's experimental Ebola vaccine.

Year-to-date stock performance: Shares of J&J are up 2.6%.



Moderna

Type: RNA-based vaccine

Stage: Phase 1

Name: mRNA-1273

Investment made: \$483 million by BARDA for vaccine development program

Background: Moderna received funding from CEPI in January to develop an mRNA vaccine against COVID-19. On February 24, it said it had shipped the first batch of mRNA-1273 to the NIAID for a phase 1 clinical trial in the U.S.

Clinical trials: The first patient in the phase 1 trial received a dose of the vaccine candidate on March 16. The study is expected to enroll 45 healthy adult patients, between the ages of 18 and 55 years old, in an open-label phase I clinical trial to test mRNA-1273 as a vaccine for COVID-19. Participants will be followed for one year. The trial, which is expected to conclude June 1, 2021, will be conducted at Kaiser Permanente Washington Health Research Institute in Seattle. CEPI funded the manufacturing of the investigational vaccine for the first phase of the trial, which is evaluating different doses for safety and immune response. A phase 2 trial is expected to begin in the second quarter.

In mid-April, Moderna said it will receive up to \$483 million in BARDA funding to support its vaccine development program. "We believe that we would be able to supply millions of doses a month in 2020 and with further investments, tens of millions a month in 2021, if the vaccine candidate is successful in the clinic," Moderna CEO Stéphane Bancel said at the time.

Year-to-date stock performance: Moderna's shares have gained 146.8%.



Novavax

Type: Vaccine

Stage: Phase 1 clinical trial

Name: NVX-CoV2373

Investment made: \$4 million from CEPI

Background: Novavax, a preclinical biotechnology company, announced February 26 that it had several vaccine candidates in preclinical animal studies. By April 8, the company said it had identified a COVID-19 vaccine candidate, and it planned to initiate a Phase I clinical study in mid-May. The first phase of the placebo-controlled study was to enroll 130 healthy adults; the first round of data from that study is expected in July.

In March the company said it had received \$4 million from CEPI to develop a COVID-19 vaccine and that Emergent BioSolutions Inc. would support contract development and manufacturing for the experimental vaccine.

Year-to-date stock performance: The company's stock has gained 334.4%.

REGENERON

Regeneron Pharmaceuticals

Type: Prevention and treatment

Stage: Preclinical

Name: REGN-COV2

Background: On February 4, Regeneron Pharmaceuticals announced it is working on developing monoclonal antibodies as treatments for COVID-19, and during a May 5 earnings call it disclosed the name of the treatment, REGN-COV2. The company's VelocImmune platform uses genetically engineered mice with humanized immune systems in preclinical testing. "We are aiming to have hundreds of thousands of prophylactic doses ready for human testing by end of August," a spokesperson said. Christos Kyratsous, vice president of infectious disease research and development and viral vector technology, is running the project.

Clinical trials are expected to begin in June.

Year-to-date stock performance: Regeneron's shares are up 37.0%.



Sanofi

Type: Vaccines

Stage: Preclinical

Name: No name yet

Background: As of February 18, Sanofi has been working with BARDA to test a preclinical vaccine candidate for severe acute respiratory syndrome (SARS) for COVID-19 using its recombinant DNA platform. A spokesperson said Sanofi aims to put a vaccine into a phase 1 clinical trial between March 2021 and August 2021. It announced a separate program with Translate Bio on March 27 to develop a mRNA vaccine.

The French drugmaker has a long history of producing vaccines in its Sanofi Pasteur business and acquired this candidate through its 2017 acquisition of Protein Sciences for \$750 million. It previously worked with the organization on flu vaccines. Scientists in Meriden, Connecticut, are working on the vaccine; David Loew, Sanofi Pasteur's Executive Vice President, is leading the project.

Year-to-date stock performance: Shares of Sanofi are down 0.7%.



Vaxart

Type: Vaccine

Stage: Preclinical

Background: Vaxart was one of the first companies to announce plans to develop a vaccine when it did so on January 31. In March, the clinical-stage company announced that Emergent BioSolutions will help develop and manufacture its oral vaccine candidate.

"We believe an oral vaccine administered using a room temperature-stable tablet may offer enormous logistical advantages in the rollout of a large vaccination campaign," Vaxart CEO Wouter Latour said in a March 18 news release.

The company plans to start a phase 1 clinical trial in the U.S. in the second half of 2020, a company executive said. As of March 31, it has five vaccine candidates for preclinical testing.

Year-to-date stock performance: Vaxart's stock is up 621.8%.

Adapted from marketwatch.com

