These 21 companies are working on coronavirus treatments or vaccines — here's where things stand

Jaimy Lee

A mix of legacy drugmakers and small startups have stepped forward with plans to develop vaccines or treatments that target the infection caused by the novel coronavirus.

COVID-19, which was first detected in December in Wuhan, China, has sickened more than 1.5 million people worldwide and killed more than 89,000. There are no Food and Drug Administration-approved vaccines or therapies for the disease although the regulator on March 29 granted an emergency use authorization to hydroxychloroquine sulfate and chloroquine phosphate to treat COVID-19 patients. The emergency rules require patients to receive doses of the drugs donated to the U.S. federal stockpile by drug manufacturers or through clinical trials.

Read more of MarketWatch's coverage of COVID-19.

In the U.S., many of the companies that are initiating 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 that has provided millions of dollars in funding to vaccine makers. Other companies are funding trials by themselves or through partnerships with other life sciences companies.

Here are some of the companies developing treatments or vaccines in the U.S. for COVID-19:

Companies: Amgen Inc. AMGN, +4.10% and Adaptive Biotechnologies Corp. ADPT, -0.59%

Type: Treatment

Stage: Preclinical

Background: The very early-stage collaboration seeks to discover and develop antibodies that can be used to prevent or treat COVID-19. Financial terms of the exclusive collaboration will be finalized "in the coming weeks," the companies said April 2. "Working with Adaptive and using their viral-neutralizing antibody platform will expedite our ability to bring a promising new medicine into clinical trials as quickly as possible," Robert Bradway, Amgen's chairman and CEO, said in a

statement.

Year-to-date stock performance: Amgen's stock is down 9.9%; Adaptive's has dropped 15.3%.

Companies: BioNTech SE BNTX, +0.54% and Pfizer Inc. PFE, -0.25%

Type: Vaccine

Stage: Preclinical

Name: BNT162

Background: On March 17, Pfizer announced that it would help develop and distribute BioNTech SE's COVID-19 vaccine candidate, though the deal excludes China. The companies plans to put the vaccine candidate into clinical trials in late April, in Germany and the U.S. As part of the deal, Pfizer will pay $185 million upfront, with additional possible future milestone payments of up to $563 million. BioNTech is also testing the vaccine in collaboration with Shanghai Fosun Pharmaceutical Group Co. Ltd. in China. Pfizer and BioNTech for several years have said they would partner to develop mRNA-based influenza vaccines.

Year-to-date stock performances: Shares of BioNTech have soared 45.5%; Pfizer's stock is down 9.9%.

Name: CalciMedica Inc.

Type: Treatment

Stage: Phase 2

Name: CM4620-IE

Background: The privately held clinical-stage company is testing an investigational drug in 60 patients with severe COVID-19 pneumonia and who are at risk for their disease to progress to acute respiratory distress syndrome (ARDS). The open-label, Phase 2 trial is taking place at Regions Hospital in St. Paul, Minn., and Henry Ford Hospital in Detroit. "It has the potential to prevent the development of ARDS in patients with severe COVID-19 pneumonia and reduce the need for ventilators at a time when there is a shortage of ventilators in health care facilities across the U.S.," Dr. Charles Bruen, a critical care and emergency physician at Regions Hospital, said in an April 9 news release.

Company: CytoDyn Inc. CYDY, -3.75%

Type: Treatment

Stage: Phase 2 clinical trial

Name: leronlimab

Background: CytoDyn, a preclinical biotechnology company based in Vancouver, said March 31 that the FDA is allowing a mid-stage trial for its experimental drug

leronlimab in COVID-19 patients to move forward. The investigational therapy has not been approved for any indications; for COVID-19, it's being proposed as a treatment for mild-to-moderate respiratory complications that occur in patients with the disease. The randomized, double-blind, placebo-controlled study will test the efficacy and safety of leronlimab in 75 patients. CytoDyn had been studying the experimental therapy as a treatment for people with HIV and a form of metastatic breast cancer.

Year-to-date stock performance: CytoDyn's stock has soared 180.0%.

Company: Dynavax Technologies Corp. DVAX, +9.09%

Type: Adjuvant platform for vaccines

Background: Dynavax said in March that it's making its adjuvant technology available to companies developing COVID-19 vaccines through a partnership with CEPI. Dynavax's adjuvant technology can help provide an increased immune response to a vaccine; the biopharmaceutical company is also working with the University of Queensland, Australia, on vaccine development through a CEPI deal.

Year-to-date stock performance: Its stock is down 46.8%.

Company: Gilead Sciences Inc. GILD, +2.55%

Type: Treatment

Stage: Phase 3 clinical trials

Name: remdesivir

Background: Gilead is a longtime drugmaker best known for developing the first major cure for hepatitis-C in Sovaldi, a therapy that changed the standard of care for that disease but also kicked off the national debate about drug pricing. The company has experience developing and marketing HIV drugs, including Truvada for pre-exposure prophylaxis (PrEP), its preventive HIV medicine. Along with U.S. trials, Gilead is conducting a randomized, controlled clinical trial in Wuhan, testing remdesivir as a treatment for mild-to-moderate forms of pneumonia in people with the virus. The trial was given the go-ahead by China's Food and Drug Administration in February. Gilead in late March halted individual compassionate use requests for remdesivir as outbreaks worsened in the U.S., having provided the investigational therapy to 1,000 patients. "The system cannot support and process the overwhelming number of applications we have seen with COVID-19," Gilead CEO Daniel O'Day said March 28. The company said in April it aims to have 500,000 treatment courses manufactured by October and 1 million by the end of 2020.

Clinical trials:

1. As of April 9, the National Institute of Allergy and Infectious Diseases is enrolling patients in a randomized, double-blind, placebo-controlled Phase 2 trial evaluating 440 hospitalized patients with COVID-19 at up to 75 sites worldwide, including at three sites in Singapore and South Korea. However, the majority of the study locations are in the U.S. The study began Feb. 21 and is expected to conclude April 1,

2023. Previously listed U.S. sites include the National Institutes of Health in Bethesda, Md., the University of Nebraska Medical Center in Omaha, the University of Texas Medical Branch in Galveston, and Providence Sacred Heart Medical Center in Spokane.

2. As of April 9, Gilead said a randomized, open-label Phase 3 trial will evaluate remdesivir in 1,600 patients with moderate COVID-19. It previously said it would enroll 600 participants. The trial started enrolling patients in March, with results to come in May. The clinical trial listing states the study is taking place in 13 countries, including Hong Kong, Singapore, South Korea and the U.S.

3. As of April 9, Gilead said a randomized, open-label Phase 3 trial will evaluate remdesivir in 2,400 patients with severe COVID-19. The drugmaker previously said it planned to include 400 participants in the trial. The trial starts enrolling patients in March, with results expected in May. The clinical trial listing states the study is taking place in Hong Kong, Singapore, South Korea and the U.S.

Year-to-date stock performance: Shares of Gilead are up 13.2%.

Company: GlaxoSmithKline GSK, +4.97%

Type: Pandemic adjuvant platform for vaccines

Name: AS03 Adjuvant System

Background: GSK is another leading vaccine maker, having brought to market vaccines for human papillomavirus (HPV) and the seasonal flu, among others. On Feb. 3, it said the CEPI-funded University of Queensland will have access to the British drugmaker's vaccine adjuvant platform technology, which is believed to both strengthen the response of a vaccine and limit the amount of vaccine needed per dose. On Feb. 24, GSK said that Clover Biopharmaceuticals Inc., a Chinese biotechnology company, 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 Inc. 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 18.7%.

Company: Heat Biologics Inc. HTBX, +8.25%

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. 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 9.4%.

Company: Inovio Pharmaceuticals Inc. INO, +10.50%

Type: DNA-based vaccine

Timeline: Phase 1 clinical trial

Name: INO-4800

Background: Another CEPI grantee, awarded $9 million, Inovio has begun 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.

Timeline: Inovio develops immunotherapies and vaccines but hasn't yet had a product approved for treatment. For INO-4800, preclinical testing was performed between Jan. 23 and Feb. 29. The company began clinical trials in the U.S. with up to 40 participants in April, dosing the first patient on April 6. It has said it plans to launch human trials in China and South Korea that same month, and says that it has a total of 3,000 doses prepared for the trials in the three countries. 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 additional clinical trials or emergency use by the end of the year. Inovio on March 12 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 Inc., 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 147.9%.

Company: Johnson & Johnson JNJ, +1.36%

Type: Vaccine

Name: TBD

Background: J&J announced Feb. 11 it was working with BARDA to test its vaccine candidate, with each organization providing $1 billion for research and development and the public-health organization funding the Phase 1 trials. 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. "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." J&J also 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.

Timeline: 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.

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

Company: Moderna Inc. MRNA, +8.99%

Type: RNA-based vaccine

Stage: Phase 1

Name: mRNA-1273

Background: Moderna received funding from CEPI in January to develop an mRNA vaccine against COVID-19. On Feb. 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. It's expected to conclude June 1, 2021. Participants will be followed for one year. The trial 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. "It's pretty important that we do this in a placebo-controlled scientifically sound design so that once those trials read out, we actually conclusively know and can demonstrate both the efficacy and overall safety profile of this vaccine," Moderna chief medical officer Tal Zaks said during a March 30 call with investors, according to a FactSet transcript.

Year-to-date stock performance: Moderna's shares have gained 64.6%.

Company: Novavax Inc. NVAX, +3.25%

Type: Vaccine

Stage: Phase 1 clinical trial

Background: Novavax, a preclinical biotechnology company, announced Feb. 26 it had several vaccine candidates in preclinical animal studies. In April, the company said it had identified a COVID-19 vaccine candidate, and it plans to initiate a Phase I clinical study in May. The first phase of the placebo-controlled study will 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. EBS, +1.56% would support contract development and manufacturing for the experimental vaccine.

Year-to-date stock performance: Its stock has gained 338.5%.

Company: Regeneron Pharmaceuticals Inc. REGN, +5.51%

Type: Treatment

Stage: Preclinical

Name: No name yet

Background: On Feb. 4, Regeneron announced it is working on developing monoclonal antibodies as treatments for COVID-19. 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, VP of infectious disease R&D and viral vector technology, is running the project.

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

Companies: Regeneron Pharmaceuticals and Sanofi

Type: Treatment

Stage: Phase 2/3 clinical trial

Name: Kevzara

Background: The FDA previously approved Kevzara, a treatment developed by Regeneron and Sanofi, as a therapy for rheumatoid arthritis in 2017 as part of a recently concluded longstanding R&D partnership between the two companies.

Clinical trials: The companies said March 16 they had started a Phase 2/3 trial testing Kevzara as a treatment for patients who have been hospitalized with severe COVID-19 infections. This randomized, double-blind, placebo-controlled trial is expected to enroll up to 400 patients and will take place at 16 sites in the U.S. New York's Mount Sinai Hospital, the first site, has started enrolling patients, according to a company spokesperson. The aim is to evaluate if the drug lessens patient fevers and their need for supplemental oxygen. The Phase 3 trial will evaluate if Kevzara prevents deaths and reduces need for mechanical ventilation, supplemental oxygen, or hospitalization. Early results from a small 21-person trial in China that have not been peer-reviewed found that COVID-19 patients reported reductions in fever and 7% of them had a reduced need for supplemental oxygen within days of starting treatment. On March 30, the companies said the first patient in their global trial had been treated. The patient is not located in the U.S., though the Phase 2/3 trial is being conducted in seven countries, including the U.S

Company: Roche Holding AG ROG, +3.18%

Type: Treatment

Stage: Phase 3

Name: Actemra

Background: Roche's Actemra was first approved in 2010 as a rheumatoid arthritis drug. The Swiss drugmaker has initiated a Phase 3 clinical trial evaluating Actemra as a treatment for patients with COVID-19 who have been hospitalized with severe pneumonia. Roche began enrolling around 330 patients in early April, at 55 sites in the U.S. and elsewhere in the world. On April 3, the first patients in the trial were treated, a Roche spokesperson said by email. The company plans to examine patient mortality and need for mechanical ventilation or an intensive care unit stay among other primary and secondary endpoints. The trial is in partnership with BARDA.

Year-to-date stock performance: Roche's stock is down 1.3%.

Companies: Sanofi SNY, +2.17% and Translate Bio Inc. TBIO, -1.29%

Type: Vaccines

Stage: Preclinical

Name: No name yet

Background: Starting Feb. 18, Sanofi is working with BARDA to test a preclinical vaccine candidate for severe acute respiratory syndrome (SARS) for COVID-19 using its recombinant DNA platform. It 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. The French drugmaker previously worked with the organization on flu vaccines. Scientists in Meriden, Ct., are working on the vaccine; David Loew, Sanofi Pasteur's EVP, is leading the project. Sanofi announced a separate program with Translate Bio Inc. TBIO, -1.29% on March 27 to develop a mRNA vaccine.

Timeline: A spokesperson said Sanofi aims to put a vaccine into a Phase 1 clinical trial between March 2021 and August 2021.

Year-to-date stock performance: Shares of Sanofi are down 10.7%.

Company: Takeda Pharmaceutical Company Ltd. TAK, -1.31%

Type: Treatment

Stage: Preclinical

Name: TAK-888

Background: The Japanese drugmaker said March 4 it plans to test hyperimmune globulins for people who are at high risk for infection. As part of its research, which will be performed in Georgia, Takeda said it would need access to plasma from people

who have recovered from COVID-19 or those who have received a vaccine if one is developed. Dr. Rajeev Venkayya, president of Takeda's vaccine business, is the co-lead of the company's COVID-19 response team. Like J&J, Takeda plans to examine whether other therapies, both experimental or with regulatory approval, may have treatment potential. In April, Takeda and CSL Behring CSLLY, +2.09% said they formed an alliance to develop a plasma-derived treatment for COVID19. Biotest AG and Octapharma also joined the alliance.

Year-to-date stock performance: Shares of Takeda are down 19.3%.

Company: Vaxart Inc. VXRT, -4.41%

Type: Vaccine

Stage: Preclinical

Background: Vaxart was one of the first companies to announce plans to develop a vaccine when it did so Jan. 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 393.6%.

Company: Vir Biotechnology Inc. VIR, +0.20%

Type: Treatments

Stage: Preclinical

Background: In many ways, Vir has been one of the most prolific partners in the biotech field during the pandemic. The preclinical company is run by George Scangos, the former CEO of Biogen Inc. BIIB, +3.48%. Starting Feb. 25, it said it was collaborating with Shanghai-based WuXi Biologics to test monoclonal antibodies as a treatment for COVID-19. If the treatment is approved, WuXi will commercialize it in China, while Vir will have marketing rights for the rest of the world. It later announced a partnership with Biogen to help develop and manufacture its monoclonal antibodies as a potential treatment for COVID-19. Biogen will handle clinical manufacturing of Vir's antibodies, the company said. Vir later announced a research agreement with Generation Bio as part of its COVID-19 antibody development program. And most recently it announced the equity investment from GSK.

Year-to-date stock performance: Vir shares have jumped 124.2%.