Money Talks by Dave Helscher
May 2020

Hundreds of companies are racing to develop vaccines and drug therapies that could help end the COVID-19 pandemic. News reports on successful or failed trials affect individual stock prices and can trigger swings in the broader market. Understandably, this highly contagious virus and its severe economic repercussions has a knack for stirring up investors' emotions. This virus is responsible for more than 100,000 deaths in the U.S. Investors are human beings first and most are waiting anxiously for a cure that will stop the suffering and allow normality to resume.

Governments and nonprofits have provided billions of dollars in support to speed a costly, complex, and time-consuming drug development process. Even so, this influx of public funding and a concerted humanitarian effort suggests that some of the most important discoveries may not generate profits for investors.

A vaccine prepares the body's immune system to recognize and resist a specific disease. As of the end of May, the World Health Organization was tracking 125 experimental vaccine candidates globally, 10 of which had advanced to clinical evaluation. Another 115 candidates are still in the pre-clinical stage, which involves testing in cells or animals and waiting for regulators to review results and grant permission for human trials. Clinical studies are conducted in 3 phases. Phase 1 is a small study of healthy people testing the safety and immune response of the vaccine at different doses. Phase 2 is a randomized, double-blind, controlled study of hundreds of people that further assesses safety, efficacy, and optimal dosing. If all goes well, Phase 3 expands clinical studies to include thousands of people. Larger studies can be challenging because they test how well the vaccine works in an environment where the virus is spreading. Despite the urgency, COVID-19 vaccine candidates can't skip any of these crucial steps, but timelines have been accelerated. Health officials have estimated it could take 12 to 18 months before a vaccine may be available.

The U.S. government is working with pharmaceutical companies, supporting research in leading candidates and boosting the manufacturing capacity needed to produce 300 million doses by this fall, should a candidate prove effective. The public investment in this process allows getting a head start on manufacturing doses while waiting for human trials to conclude. In return, at least one drug maker has promised to sell an approved vaccine without making a profit during the pandemic. The Director of National Institute of Allergy and Infectious Diseases recently stated that they will fund and conduct three Phase 3 trials starting this summer. This is a relatively rapid progress of advancing the vaccines through the early stages of testing. Also, historically many vaccine candidates fail to make it through all phases of trials. Researchers hope the trials will yield answers within 6 – 8 months of their start.

The development and approval process for experimental drugs is similar to the one for vaccines. Companies that develop successful treatments are likely to face the same manufacturing challenges and pricing pressures. In the meantime, existing therapies are being tested that might help COVID-19 patients. Effective antibody drugs are easier to develop but more complex to manufacture. There is

limited global capacity to produce the large amounts needed. There are discussions among concerns that are normally competitors for ways to share manufacturing plants if one company's antibody proves to work better than others. Antibody treatments could help save lives, but widespread vaccination could make them obsolete. If a successful vaccine materializes, many valiant efforts to develop beneficial therapies may never make much money.

It's rarely easy to predict which new products will perform well enough in multiple rounds of studies to earn regulatory approval. Moreover, the stock market's recent rally and high valuations for biotech and pharmaceutical shares imply that success in developing COVID-19 treatments might already be priced in. Headline induced price swings suggest that investors are making decisions driven by hopes and fears, and possibly based on limited information, instead of a realistic assessment of an investment's longer-term earnings potential.