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Without showing any data, CytoDyn touts treatment for Covid-19 as winner — while its CEO sells stock

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May 4, 2020

CytoDyn CEO Nader Pourhassan appearing in a promotional video about leronlimab and Covid-19.

While Nader Pourhassan, the chief executive of drug maker CytoDyn, filed his intention to sell nearly $17 million of his company's shares last Thursday, he was simultaneously pitching the same CytoDyn stock to outside investors, claiming its lead drug is saving the lives of patients with Covid-19.

Pourhassan's plan to sell more than 4.8 million shares, disclosed in an SEC filing on Friday, amounts to more than half of his ownership stake in CytoDyn. The timing of the sale is troubling and should concern, even anger, any investor who's bought CytoDyn stock based on Pourhassan's coronavirus marketing pitch.

In a civil lawsuit filed last week, a group of CytoDyn stockholders, including three former directors, accused Pourhassan and other CytoDyn insiders of "blatant self dealing" and "egregious abuse of power" by enriching themselves through "unjustified and oversized awards of company stock."

Pourhassan did not return phone calls or respond to text messages seeking comment for this article.

At the Friday close of $3.50, CytoDyn's stock price has more than tripled in value since March. Including common stock, options, and warrants, CytoDyn's market value today is greater than $2 billion. The company has zero revenue, no approved products, and mounting losses.

What CytoDyn does have, however, is a chief executive who knows retail investors are lapping up coronavirus investment pitches, no matter how scientifically implausible they might be. Starting in March, CytoDyn has issued almost daily press releases and posted numerous videos to YouTube that feature Pourhassan speaking

excitedly about the company's experimental HIV medicine called leronlimab — repurposed for use against Covid-19 — being responsible for "remarkable" recoveries of severely ill and hospitalized patients.

In a YouTube video[6] about leronlimab posted on Friday, May 1, Pourhassan said, "the potential of this product is really just stunning for us." Pourhassan describes dying patients with Covid-19 who were "saved" after receiving injections of leronlimab in the hospital; others were extubated from mechanical ventilators or discharged after just a few days following leronlimab treatment. "The whole world is worried about coronavirus, this is probably the best solution," he said.

In the video, Pourhassan doesn't mention his intention to sell more than 4.8 million shares of his CytoDyn stock the day prior.

Any insider sale requires public disclosure; and one that large, particularly by the CEO, will trigger alarm bells among outside investors. On Thursday, Pourhassan filed a Form 144, also known as a proposed sale of securities, with the SEC. Form 144 filings are only made when an individual has a "bona fide intention" to sell the listed securities "within a reasonable time," according to the SEC.

Pourhassan filed his Form 144 without also posting it to the searchable EDGAR database — which is allowed by the SEC but also makes it more difficult for the public to spot. Bloomberg and other data services that track SEC activity reported Pourhassan's paper Form 144 filing on Friday evening.

Leronlimab belongs to a class of HIV drugs called entry (or fusion) inhibitors. These drugs work by blocking the virus from entering healthy immune cells. That's different from most HIV drugs, which act against the virus after it infects immune cells. Three entry/fusion inhibitors have reached the market, but none generates significant revenue because doctors reserve their use for the small number of patients with multidrug-resistant HIV.

CytoDyn paid $3.5 million in 2012 to purchase leronlimab from another biotech company that decided to give up on its clinical development. In the ensuing eight years, CytoDyn has missed nearly all of its own deadlines for the completion of clinical trials. Necessary safety data were not collected on time, while quality control and other manufacturing issues weren't fixed. The drug was finally submitted to the Food and Drug Administration at the end of April, years behind the company's promised timeline.

Excluding its recent stock gains, CytoDyn shares were trading for 30 cents, a loss of nearly 90% over the past eight years.

The coronavirus pandemic was an opportunity for CytoDyn to change the leronlimab story. Leronlimab does not block the coronavirus from entering cells, like it purports to do with HIV; instead, the drug calms inflammation, restores the immune system, and decreases viral load, according to Bruce Patterson, the owner of a diagnostics company in the San Francisco Bay Area and a paid consultant to CytoDyn.

Patterson almost always appears alongside Pourhassan in Cytodyn's promotional videos, or he is quoted in its press releases. Most recently, Patterson called leronlimab a "triple threat" because of the three ways it fights the coronavirus, based on his personal "discoveries" that have not been published or reported yet.

But very little that Pourhassan or Patterson have said about leronlimab and Covid-19 has been independently verified. The stories of recovered patients detailed in the company's many press releases are hopeful anecdotes,

but have not been supported by clinical trial results or published scientific papers.

Leronlimab has been used to treat Covid-19 patients at some U.S. hospitals under compassionate use protocols allowed by the FDA. Whether or not the drug helped patients recover isn't known.

Last week, Pourhassan told investors that Harish Seethamraju, a physician at Montefiore Medical Center in the Bronx, saved the lives of four patients with severe Covid-19 by using leronlimab under emergency use.

"Saving four of these patients' lives was a very big achievement for Dr. Seethamraju. He told me he had no other option," other than using leronlimab, Pourhassan said.

A spokesperson for Montefiore confirmed that in March and April, patients with Covid-19, including some treated by Seethamraju, were given leronlimab under FDA-sanctioned emergency use protocols. Two patients were extubated but it was not possible to attribute improvements in their condition or recovery to leronlimab, in part because the patients were also treated with other drugs.

Seethamaraju and colleagues published a letter in the New England Journal of Medicine on April 24, documenting the treatment of 36 kidney-transplant patients diagnosed with Covid-19. Six of these patients received leronlimab, but only one patient remained in stable condition without intubation, the physicians reported. The letter made no conclusions about the efficacy or safety of leronlimab.

There have been no other studies or papers published to date in peer-reviewed medical journals about leronlimab's role in treating Covid-19. Cytodyn is conducting two clinical trials of leronlimab in Covid-19 patients, but results have not been announced.

"You want to see Covid-19 patients get real treatments based on real science and not because someone is trying to move the stock," Richard Trauger, a former CytoDyn executive from 2011 to 2013, including chief scientific officer in 2012 and 2013, told STAT.

Trauger says he was chiefly responsible for negotiating the licensing deal that brought leronlimab to CytoDyn in 2013, but he left soon after because he disagreed with the way Pourhassan was running the company.

At higher doses, leronlimab has the potential to tamp down the immune system, said Trauger, but he doubts the drug would be potent enough to benefit patients with Covid-19, especially because other immune system-suppressing drugs are likely to be more effective.

When Trauger heard that CytoDyn was pitching leronlimab as a Covid-19 treatment, he immediately thought of maraviroc, an approved HIV drug that works the same way as leronlimab. If this type of drug had potential against Covid-19, surely GlaxoSmithKline, which owns maraviroc, would be pushing it into a clinical trial.

But no such clinical trial has been started, according to ClinicalTrials.gov. Glaxo is "conducting exploratory research to see if our medicines may have the potential to demonstrate impact against the COVID-19, however it is too early to speculate on any benefit," a spokesperson said. She declined to comment specifically about maraviroc.

"There is no third-party validation that this approach will work. I think that tells you everything you need to know," said Trauger.

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