IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
v.	*	Criminal Case No. PX 22-440
NADER POURHASSAN KAZEM KAZEMPOUR,	*	

Defendants.

******

MEMORANDUM OPINION

Presently pending are motions to undo the jury verdict in this matter. Defendants Nader Pourhassan ("Pourhassan") and Kazem Kazempour ("Kazempour") separately moved for judgment of acquittal, or in the alternative, for a new trial. ECF Nos. 311 and 312. The motions are fully briefed, and after a hearing, supplemental briefing, and serious consideration, the Court DENIES the motions for judgment of acquittal, GRANTS Kazempour's motion for new trial, and DENIES Pourhassan's new trial motion.

I. Background

This case concerns the multi-year efforts of Pourhassan and Kazempour to bring an experimental drug, Leronlimab, to market for the treatment of advanced HIV-positive symptomatic patients and for COVID-19. During the relevant times, Pourhassan was the CEO of CytoDyn, a publicly traded company responsible for developing solely Leronlimab. Kazempour was the CEO of Amarex, a contract research organization with specialized experience in assisting companies like CytoDyn that seek the U.S. Food and Drug Administration ("FDA")'s approval to market new drugs. CytoDyn was Amarex's largest client. Kazempour functioned as the "regulatory agent" for CytoDyn vis the FDA. Despite Defendants' attempts to monetize

Leronlimab, FDA approval never came to pass and so, CytoDyn never generated any revenue apart from stock sales.

According to the Government, from 2018 through 2021, Defendants conspired and executed a scheme to defraud CytoDyn investors through a series of public announcements that falsely claimed Leronlimab was on the precipice of marketability so as to artificially inflate CytoDyn's stock price. After a three-week trial, the jury rendered a split verdict as to both Defendants. Now each seeks relief from the verdicts. To place the pending motions in context, the Court first summarizes the relevant trial evidence, and next the fourteen-count indictment and subsequent verdict.

II. Evidence Developed at Trial

A. Leronlimab for HIV

Central to the HIV-related fraud was CytoDyn's efforts to obtain from the FDA a license to market Leronlimab for treatment of particularly severe HIV-symptomatic patients. The research and development of a drug culminates in a "completed" Biologics License Application ("BLA") to the FDA, which the FDA then takes under consideration to determine if it will license the drug to market. ECF No. 286, Tr. Vol. 2 at 180. Once an applicant like CytoDyn submits a completed BLA, the FDA screens the submission to determine if it is sufficiently complete to permit substantive review. *Id.* at 185. If the BLA is not complete, the FDA will issue what is known as a "refuse to file" letter to the company which effectively ends the BLA process. *Id.* An application is "complete" only if it includes clinical research data of sufficient quantity and quality to allow the FDA to review the drug's safety and efficacy. *Id.* at 187. If the BLA is complete, the FDA next turns to whether it will approve the drug for licensure and distribution. *Id*. at 186.

Defendants began the BLA process in 2018 and engaged in several meetings with the FDA to ascertain the BLA requirements. ECF No. 286, Tr. Vol. 2 at 187. In June of 2018, for example, FDA representatives met with Defendants and communicated specifically that the FDA would not consider the BLA complete unless the data from the HIV-related clinical trials was submitted in a "reviewable format." *Id.* at 215. *See* also GX-600.[1] The FDA also expressed concerns with what it believed to be Defendants' overly optimistic timeline for submitting the BLA. *Id.* at 219.

The FDA met again with Defendants on December 14, 2018 to discuss CytoDyn's ongoing studies of using Leronlimab at a higher dose to treat HIV-compromised patients. ECF No. 286, Tr. Vol. 2 at 222–24. At that meeting, the FDA again voiced concerns to Defendants about the proposed timeline for the BLA submission because of dose adjustments in the clinical trials. *Id.* at 225. The FDA thus suggested that CytoDyn submit "mock" datasets to make sure the data would be reviewable, and forewarned Defendants that they could risk a "refuse to file" letter if the BLA did not include sufficient data submitted in the correct format to justify a dose change. *Id.* at 230. Kazempour acknowledged in writing the FDA's guidance. GX-21.

For the next 18 months, Defendants remained in regular contact with the FDA about the specific requirements for the BLA. ECF No. 286, Tr. Vol. 2 at 231. At the same time, Pourhassan recognized that CytoDyn could not generate revenue without securing the BLA, so to incentivize its completion, he convinced the CytoDyn Board of Directors to award him and others stock options that would vest upon the BLA's filing. ECF No. 292, Tr. Vol. 8 at 127–28.

Pourhassan next engaged in a series of text and email communications with Kazempour and Amarex's chief scientist, Dr. Kush Dhody ("Dhody"), pressing for the BLA's completion. Pourhassan particularly communicated that the delay in filing the BLA was causing the CytoDyn

[1] Trial exhibits are cited using their exhibit prefixes GX-, PX-, or KX-.

stock price to drop. On January 30, 2020, for example, Pourhassan wrote to Kazempour that they needed to file the clinical section of the BLA "as this is becoming increasingly worrisome to our investors. Today our stock was as high as $1.53 and all of a sudden we had a selloff . . . ." GX-119. On February 8, 2020, Pourhassan told Kazempour and Dhody that after having reported the BLA would be delayed until the end of February, "our stock dropped and our market cap went down by $200 million and everyone is asking for my head." GX-6. Pourhassan went on: "If we can't get BLA done by the end of February we will have another tremendous drop in our stock." *Id.* Pourhassan also communicated directly with Kazempour that CytoDyn really needed "your help with our BLA" because "I am losing a lot of credibility among our shareholders." GX-310H.

Despite this, the BLA was not yet ready to file, principally because the datasets reflecting the efficacy of Leronlimab at the new dose were not properly formatted. Pourhassan evidently became increasingly concerned about the stock price and asked Dhody at Amarex, "what will we be risking?" if the BLA was filed by no later than April 15. GX-28. *See also* GX-31. Around the same time, Pourhassan emailed Kazempour and Dhody that CytoDyn's stock price dropped "in 1 hour almost 20%" and that "[t]his drop will be much deeper if we don't file our BLA as the [stock] message board now is getting bombarded by investors who are very frustrated with me and CytoDyn." GX-2. Accordingly, Pourhassan directed them to "file the BLA no later than next week Wednesday, even if we are short in no matter what portion of whatever it is that we are short." *Id.*

Two weeks later, on April 27, 2020, Kazempour filed the BLA with the FDA. In the accompanying cover letter, Kazempour acknowledged that the submission did not include the data in the format that the FDA directed, but that "[r]evised datasets will be submitted to the BLA as an amendment in May 2020." GX-3. The letter further highlighted the specific clinical sections

of the BLA that "will be provided in [the] next amendment." *Id.* As it happens, the FDA had already received all the data previously as mock datasets. Missing was the submission in the specific format that the FDA required for the BLA review. ECF No. 287, Tr. Vol. 3 at 27, 98.

Notwithstanding the BLA's lack of completeness, CytoDyn issued a press release on the same day, April 27, announcing that it had submitted a "completed" BLA to the FDA for Leronlimab as a combination therapy for HIV. GX-35. The press release detailed that the BLA included "the clinical, and the CMC (chemistry, manufacturing and controls) portions" to the FDA. *Id.* Pourhassan is also quoted as saying that the BLA represented a "significant milestone for the Company, and initiates its transition from a development-stage company to a commercial organization." *Id.* At trial, several CytoDyn investors testified about the significance of this press release regarding their decision to invest or maintain their investments in CytoDyn. ECF No. 287, Tr. Vol. 3 at 160; ECF No. 288, Tr. Vol. 4 at 109; ECF No. 290, Tr. Vol. 6 at 162–65.

The next day, April 28, Kazempour emailed Mike Mulholland, Chief Financial Officer for CytoDyn, to inquire about selling warrants that had been issued to him in connection with his work for CytoDyn. Kazempour stated, "[s]everal years ago, [the] Board of CytoDyn gave me 150,000 share options, and after this many years, I am thinking to sell the shares now!!" GX-8. Kazempour asked Mulholland to "explain" to Kazempour or his broker "what we need to do to sell those shares." *Id.*

The day after that, April 29, the FDA directly contacted Kazempour as CytoDyn's regulatory agent to correct the April 27 press release. The FDA stated plainly that it did not consider the BLA "complete" because of missing datasets and that the FDA review clock would not start until "the applicant informs the Agency that a complete BLA was submitted." GX-38. The FDA thus demanded that Kazempour "take regulatory responsibility for the misinformation

released in the [April 27] Press Release by notifying CytoDyn" of the FDA's position and "formally retract submission of the clinical module." *Id.* Kazempour, in turn, informed CytoDyn of the FDA's position and next communicated to the FDA that the error "will be addressed in the next press release." GX-608.

On May 4 and 6, CytoDyn published two corrective press releases that acknowledged the BLA was not complete when filed on April 27. Specifically, the release stated that the BLA "will be considered completed after the clinical data sets are submitted on May 11, 2020. The clinical datasets are updated to address FDA comments for mock datasets from March 12 and March 20, 2020." GX-44 & GX-45. The subject of both press releases, however, was not the BLA. Rather each discussed the status of parallel studies of Leronlimab's use to treat COVID-19. *Id.* The corrective statement about the BLA was buried within the unrelated COVID-19 discussion.

On May 11, as promised, Kazempour and Amarex submitted the missing datasets. GX-49; ECF No. 295, Tr. Vol. 11 at 202. Two days later, CytoDyn issued a press release announcing that it has submitted the remaining datasets for the BLA and that the FDA will begin its review process to ascertain if the application is complete and ready for review. GX-47. Next on May 15, Kazempour emailed Mulholland again about selling his CytoDyn shares. GX-9. Kazempour exercised his warrants on May 22 and sold his shares on June 9 and 10, realizing a $300,000 gain. GX-59; GX-906; KX-253.

Pourhassan, for his part, sold over $15 million of CytoDyn stock between April 30 and May 4. GX-905. In connection with the stock sale, Pourhassan acknowledged his compliance with CytoDyn's insider trading policy, particularly that he did not possess material nonpublic information when initiating the trades. *E.g.*, ECF No. 291, Tr. Vol. 7 at 219. Of the revenue generated from the stock sale, Pourhassan reinvested roughly $11 million in CytoDyn to pay taxes

on the stock sale and satisfy an outstanding vendor bill, thus realizing about $4 million in personal gain. ECF No. 292, Tr. Vol 8 at 122–23, ECF No. 291, Tr. Vol. 7 at 222–23; PX-961.

On July 8, 2020, the FDA issued its "refuse to file" letter, rejecting the BLA. GX-63. The letter specifically noted that the May 11 submission did not include "all pertinent information and data needed to complete a substantive review." *Id.* CytoDyn never resubmitted a BLA for Leronlimab's treatment of HIV.

B. Leronlimab for COVID-19

While CytoDyn was trying to bring Leronlimab to market as an HIV treatment, the COVID-19 pandemic descended. In short order, the FDA gave CytoDyn permission to conduct clinical trials designed to measure the safety and efficacy of Leronlimab as an antiviral treatment for two categories of COVID-19 patients: people with mild or moderate symptoms (the "CD 10 trial") and a larger study of hospitalized and intubated COVID-19 patients (the "CD 12 trial"). GX-613. Amarex conducted the clinical trials on CytoDyn's behalf. *Id.*

By September 2020, the FDA had reviewed the CD 10 trial results and concluded that the study failed to meet its "primary, secondary end points," or study objectives, and so could not be used as a reliable therapeutic. ECF No. 293, Tr. Vol. 9 at 268; GX-620. Nor did the FDA find reliable CytoDyn's identified "trends" in symptom improvements, as reflected in Amarex's "post-hoc analysis." GX-620. Accordingly, the FDA refused to consider the request for emergency use authorization ("EUA") for the CD 10 trial and recommended that CytoDyn focus on the CD 12 trial. GX-620; ECF No. 293, Vol. 9 at 274–75.

The CD 12 trial in the FDA's estimation, however, fared no better. The clinical results of the CD 12 trial reflected that the drug had not met its primary and secondary endpoints. ECF No. 294, Tr. Vol. 10 at 5–6. Nonetheless, post hoc analysis of certain study "subgroups," according to

CytoDyn, showed therapeutic benefits to certain populations of critically ill COVID-19 patients. ECF No. 294, Vol. 10 at 7. Pourhassan next directed that Amarex submit an "addendum" to the FDA about the clinical significance of the CD 12 trial. GX-10 & GX-70. The addendum, however, omitted that the results were not statistically significant, meaning that the supposed "benefits" conferred to critically ill patients could be just as much by happenstance or some other factor apart from true therapeutic effects of Leronlimab. GX-159. *See also* ECF No. 293, Tr. Vol. 9 at 226.

Nonetheless, CytoDyn, through Pourhassan, conveyed a much different message to the investor public. For one, Pourhassan pushed through press releases and paid marketing videos that touted Leronlimab's supposed extraordinary results in treating those ill with COVID-19. On December 22, 2020, for example, CytoDyn issued a press release claiming that the CD 10 trial produced "statistically significant" positive results for treating COVID-19 based on the post hoc analyses, but omitted any mention of the trial having failed to meet its primary or secondary endpoints. GX-64. Likewise, CytoDyn reported to the investor public overly optimistic interpretations of the CD 12 data. ECF No. 294, Tr. Vol 10 at 45; PX-1614 at 2. In short order, the FDA received a slew of requests for emergency individual use of Leronlimab, ECF No. 294, Tr. Vol. 10 at 34–35, which prompted the FDA to become increasingly concerned that CytoDyn had been misleading patients and physicians about the efficacy of the drug as a COVID-19 treatment. ECF No. 293, Tr. Vol. 9 at 281.

Pourhassan also propped up a rosy and misleading narrative about Leronlimab's efficacy in the company's SEC filings. Attached to the annual SEC Form 8-k[2], filed on March 8, 2021, Pourhassan submitted a lengthy summary of the CD 12 trial results. The summary did not disclose that the trial failed to meet primary and secondary endpoints. GX-5; ECF No. 292, Tr. Vol. 8 at

[2] SEC filings are made available through the SEC's EDGAR database, https://www.sec.gov/search-filings.

142. But it *did* represent that based on the studies "there is a high likelihood that critically ill COVID-19 patients may benefit from leronlimab added on to SoC treatments." GX-5A at 9; ECF No. 292, Tr. Vol. 8 at 142. Pourhassan also issued similar press releases that boasted about the continued safety and efficacy of the drug for "severe-to-critical patients." GX-71 (March 5, 2021), GX-52 (March 30, 2021). Notable spikes in trading volume and price tracked these releases. GX-902.

On May 17, 2021, the FDA, in response, posted to its website a public announcement that the CD 10 and CD 12 trials "do not support the clinical benefit of leronlimab for the treatment of COVID-19," and that any benefit experienced within "small subgroups" had "well-established limitations," and so cannot be said to "show a benefit in the overall study population." GX-636. Despite this, Pourhassan continued to issue written and video statements praising the drug's benefit with severely ill COVID-19 patients. In one promotional video, Pourhassan announced that "this product blows every scientist's mind" and that he is "very happy with everything" related to Leronlimab. GX-1A; GX-1B. Pourhassan particularly characterized the effect of Leronlimab on COVID-19 patients as "nothing short of spectacular." He explained,

> It' s going for critical population, mild population, long hauler. That's three critical, three, three COVID-19 trials that we are now very confident that we could hit primary endpoint due to all the studies we have done.

GX-1A.

In another video posted on September 22, 2021, Pourhassan celebrated a trial "of 394 patients which included severe and critically ill population [and] [i]n the critically ill population, our results were really strong . . . . the survival rate was 78%. Once we gave them another dose, the survival rate went up to 82%." GX-53A.

The FDA never approved Leronlimab for treatment of COVID-19 as to any population.

C. The Indictment and Verdict

At trial, the jury had to decide fourteen criminal charges alleged in the forty-page speaking Indictment. ECF No. 185.[3] Thirty-two of the forty pages are devoted to Count 1, which charged a factually dense, multi-year conspiracy between Kazempour and Pourhassan encompassing the entirety of the alleged securities and wire frauds. *Id.* at 1–32. In Counts 2 through 5, the Indictment charged substantive securities fraud as follows:

COUNT	DATE	INTERSTATE COMMUNICATION
2	4/14/2020	**POURHASSAN** sent the email to **KAZEMPOUR** and Amarex Executive 1, as described in Paragraph 44 above.
3	4/27/2020	**KAZEMPOUR** and Amarex filed an incomplete BLA on CytoDyn's behalf with the FDA, as described in Paragraph 46 above.
4	8/14/2020	**POURHASSAN** and **KAZEMPOUR** caused CytoDyn to submit its annual SEC filing on SEC Form 10-K, as described in Paragraph 58 above.
5	3/8/2021	**POURHASSAN** and **KAZEMPOUR** caused CytoDyn to file an SEC form 8-K as described in Paragraph 66 above.

ECF No. 185 at 33. Counts 6 through 10 charged multiple counts of wire fraud as follows:

COUNT	DATE	DEFENDANT	INTERSTATE WIRE COMMUNICATION
6	2/8/2020 12:33:43 PM	**NADER POURHASSAN**	Electronic message from **POURHASSAN** (x4173) to **KAZEMPOUR** (x0800) and Amarex Executive 1 (x3264)
7	4/14/2020	**NADER POURHASSAN**	E-mail from **POURHASSAN** to Amarex Executive 1 and **KAZEMPOUR**, with cc to CytoDyn Executive 2; Subject: "BLA submission"
8	4/28/2020	**KAZEM KAZEMPOUR**	E-mail from **KAZEMPOUR** to CytoDyn Executive 3, with cc to **POURHASSAN** and **KAZEMPOUR's** financial advisor; Subject: "CytoDyn: Proposed final press release for regulatory approval"
9	5/16/2020	**KAZEM KAZEMPOUR**	E-mail from **KAZEMPOUR** to CytoDyn Executive 3, with cc to **POURHASSAN** and

[3] Technically, the Defendants went to trial on a Superseding Indictment, but for brevity, the Court will refer to it as the "Indictment" or the "charges." ECF No. 185.

			KAZEMPOUR's financial advisor; Subject: "the warrant shares"
10	2/23/2021	**NADER POURHASSAN**	Email from **POURHASSAN** to **KAZEMPOUR**, and others, with the subject line "CytoDyn Leronlimab D12 COVID-19 Executive Summary Addendum FINAL," instructing **KAZEMPOUR** to submit the Addendum to the FDA

Id. at 35. The Indictment further charged solely Pourhassan with three insider trading counts:

COUNT	DATE	TRANSACTION
11	4/30/2020	Sale of approximately 2.2 million shares of CytoDyn stock valued at approximately $7.8 million
12	5/1/2020	Sale of approximately 1.39 million shares of CytoDyn stock valued at approximately $4.5 million
13	5/4/2020	Sale of approximately 1.2 million shares of CytoDyn stock valued at approximately $3.3 million

Id. at 37. Lastly, the Indictment alleged in Count 14 that Kazempour made materially false statements to an FBI agent during a July 7, 2021 investigative interview based on Kazempour's telling the agent that he owned only a couple hundred shares of CytoDyn stock when, in fact, he had possessed much more. *Id.* at 38.

After three weeks of testimony and five days of deliberation, the jury acquitted Pourhassan and Kazempour of conspiracy (Count 1). As to Pourhassan, the jury convicted him on all substantive securities fraud counts (Counts 2 through 5), two of the three wire fraud counts (Counts 7 & 10), and all three insider trading counts (Counts 11 through 13). ECF No. 280.

The verdict as to Kazempour, however, was the mirror opposite. The jury *acquitted* Kazempour of all counts save for two: one count of securities fraud based on Kazempour's April

27, 2020 BLA submission (Count 3), and one count of wire fraud based on the April 28, 2020 email he sent about selling CytoDyn warrants (Count 8). ECF No. 282.

Defendants now move for judgment of acquittal on all counts pursuant to Federal Rule of Criminal Procedure 29, or alternatively, for a new trial pursuant to Rule 33. The Court first turns to the Rule 29 motions, discussing each Defendant separately.

III. Motions for Judgment of Acquittal

On a motion for judgment of acquittal, the Court may grant relief on the grounds of insufficient evidence "if no rational trier of fact could have agreed with the jury." *Coleman v. Johnson*, 566 U.S. 650, 651 (2012) (quoting *Cavazos v. Smith*, 565 U.S. 1, 2 (2011)). When assessing whether any rational juror could have convicted a defendant, the Court must view the evidence in the light most favorable to the Government. *United States v. Tresvant*, 677 F.2d 1018, 1021 (4th Cir. 1982). The Court must allow the verdict to stand if, when drawing all inferences in favor of the Government, "substantial evidence" nonetheless supports the conviction. *United States v. Burgos*, 94 F.3d 849, 862 (4th Cir. 1996) (quoting *Glasser v. United States*, 315 U.S. 60, 80 (1942)). *See also United States v. Mitchell*, 177 F.3d 236, 240 (4th Cir. 1999) (reversing judgment of acquittal, finding the "jury heard [defendant's] version of the events and the Government's; it apparently believed the Government's version."). On a Rule 29 motion, the Court may not pass on witness credibility and must assume that all factual contradictions were resolved in favor of the Government. *United States v. United Med. & Surgical Supply Corp.*, 989 F.2d 1390, 1402 (4th Cir. 1993).

With this standard in mind, the Court first turns to Kazempour's motion.

A. Kazempour

As to Count 3, the wire fraud count concerning the April 27, 2020 BLA submission, Kazempour contends that no reasonable juror could have concluded he acted with the specific intent to defraud because the FDA "already had in hand the datasets" and because nothing shows that Kazempour personally ever reviewed or approved the April 27 press release touting the completion of the BLA. ECF No. 311-1. The Court is not persuaded.

The critical question before the jury was whether Kazempour's electronic submission of the BLA, in concert with CytoDyn claiming the BLA to be "complete," constituted a fraud on CytoDyn investors. Simply because the FDA had the underlying data in *some* form did not make the BLA "complete," or so the jury could have concluded. The FDA also had clearly instructed Kazempour and Pourhassan of the requirements for submitting a *complete* BLA, to include the data that was formatted according to FDA specification. ECF No. 287, Tr. Vol. 3 at 153–54. Equally relevant, the FDA told Defendants that the BLA review process only begins upon submitting a complete BLA. *Id.* at 32, 34.

As a variation on that argument, Kazempour also presses that no reasonable juror could have concluded that the omission of "reformatted datasets" mattered to the reasonable investor. ECF No. 311-1 at 33. The jury was correctly instructed that "[f]or a fact to be considered material, there must be a substantial likelihood that a reasonable investor would consider the fact important in deciding whether to buy or sell the security or would have viewed the total mix of information available to them to be significantly altered by disclosure of the fact." ECF No. 264 at 30. To the testifying investors, the completeness of the BLA *did* matter to them. *See* ECF No. 288, Tr. Vol. 4 at 154:15–20, 166:5–168:2 (Kang), 128:18–25 (Lonsford); ECF No. 287, Tr. Vol. 3 at 160:19–161:3 (Horvath); ECF No. 290, Tr. Vol. 6 at 165:4–16 (Munves). Kazempour's argument in this

regard thus amounts to a disagreement with the verdict rather than a claim rooted in insufficient evidence.

Kazempour also knew from Pourhassan that filing the BLA on April 27, "no matter what, even if short," was critical to maintaining the stock price. GX-119; GX-6; GX-30; GX-310H; GX-2. From this, a reasonable juror could conclude that at a minimum, Kazempour aided and abetted Pourhassan's securities fraud by knowingly filing the BLA when it was not "complete" in the sense that it did not comport with the FDA's filing requirements.

Nor is it a fair inference from the evidence that Kazempour had been unaware of the contents of the April 27 press release, at least that it was falsely communicating the BLA was "complete" for purposes of FDA review. While Kazempour emphasizes that Dhody, not he, reviewed the contents of the specific release, the evidence also showed that Kazempour and Dhody communicated about the timing of the release and Dhody's final approval of it. GX-34. This, in combination with the evidence that Kazempour and Pourhassan were in constant communication about the BLA, the contents of press releases, the issuance of the April 27 release, and the influence it would likely have on the stock price, permit the reasonable inference that Kazempour knew the press release would falsely state the BLA was complete when it was not. *See* ECF No. 292, Tr. Vol. 8 at 62:21–63:2.

As to Count 8, securities fraud premised on Kazempour's April 28 inquiry about selling his warrants, Kazempour argues that he acted in "good faith." ECF No. 311-1 at 23. But the jury had been properly instructed on the defense of good faith and rejected its application. Given that the evidence supports that he aided and abetted Pourhassan to mislead about the BLA just the day before, a reasonable juror could conclude that Kazempour's attempted exercise of the warrants the

next day was for his own financial benefit, and thus reflected fraudulent intent to profit from an artificially inflated stock price. Kazempour's motion for judgment of acquittal is thus denied.

B. Pourhassan

Pourhassan advances four main arguments in favor of acquittal. Like Kazempour, he contends that the Government "failed to negate the avalanche of evidence that he acted in good faith," thus warranting reversal on all counts of conviction. ECF No. 312-1 at 9–14. Second, he contends that the Government failed to prove his "specific intent" to defraud as to the securities and wire fraud counts. *Id.* at 11–15. Third, he claims that evidence on materiality of the alleged false statements to the public is lacking because most statements were aspirational or "forward-looking" and thus "not actionable as a matter of law." *Id.* at 33–35. Fourth, Pourhassan contends that investor witness testimony was insufficient to demonstrate the materiality of the statements made to the investor public. *Id.* at 16–26. The Court takes each contention in turn.

To begin, the good faith argument fails because the jury had been properly instructed on good faith and the Government's ultimate burden to disprove the same. Pourhassan's arguments now amount to little more than selectively emphasizing favorable evidence while ignoring the wealth of other evidence supporting guilt. For example, Pourhassan stresses that he personally "believed" the BLA was "complete when filed." ECF No. 312-1 at 11. Certainly, some evidence supports that inference. But other evidence does not, such as his entreaty to "file the BLA . . . even if we are short in no matter what portion of whatever it is that we are short"; this alone permits a reasonable juror to draw an inference of guilt and reject claims of "good faith." GX- 2.

Pourhassan similarly emphasizes Dhody's testimony that Dhody viewed the BLA as "complete" and thus found no impediment to characterizing the BLA as "complete." ECF No. 296, Tr. Vol. 12 at 70:1–2, 75:10–17. At best, Dhody and other scientists supported Pourhassan's

counter narrative. But the jury also had FDA witnesses and contemporaneous documents reflecting that from the perspective of the agency responsible for reviewing the BLA, the application was decidedly *not* complete, and the Defendants knew it would not be considered complete at the time they filed it. The jury simply resolved these evidentiary conflicts in favor of guilt. *See United States v. Dinkins*, 691 F.3d 358, 387 (4th Cir. 2012).

As for the COVID-19 allegations, again Pourhassan stresses the evidence that points in favor of his personal belief that Leronlimab was effective in battling COVID-19 and argues from there that the statements to the investor public that the drug "saves lives" were made in good faith. ECF No. 312-1 at 12. But this alone does not rebut the Government's proof that Pourhassan omitted from the SEC filings and press releases that the COVID-19 clinical trials *failed* to meet its endpoints, or that the FDA would not grant an EUA. GX-630. The jury was entitled to, and did, credit the solid counter evidence to Pourhassan's belief in the drug's efficacy.[4]

As to the "forward-looking" quality of certain statements, Pourhassan often did express hope and optimism about the future of Leronlimab as a safe, effective treatment for HIV and COVID-19. *E.g.*, ECF No. 286, Tr. Vol. 2 at 220:12–221:25; ECF No. 287, Tr. Vol. 3 at 254:1–15; ECF No. 290, Tr. Vol. 6 at 231:15–25. But not *all* statements were such. More to the point, the jury had been plainly instructed that forward-looking statements could not form the basis of the fraud charges. ECF No. 264 at 30 (Jury Instruction No. 39). Pourhassan was also given wide latitude to develop the evidence and argue this as the very reason he was entitled to acquittal. Thus, as with his good faith argument, that the jury disagreed does not support setting aside the verdict.

[4] The "good faith" argument as to the insider trading counts suffers from the same flaws. ECF No. 312-1 at 13. The Court gave Pourhassan ample runway to demonstrate that he exercised his options not for personal gain but to pay CytoDyn's debts. *E.g.*, PX-961; ECF No. 292 at 176, 178–79. However, Pourhassan also netted significant personal wealth from the stock sales and this, in combination with the remaining evidence, amply supports the convictions.

Pourhassan's last argument is in many ways the most vexing. He disagrees that the materiality of the alleged false statements supporting the fraud counts had been sufficiently established through four individual investor witnesses. ECF No. 312-1 at 25. He argues now, as he did at trial, that the investors were not sufficiently sophisticated or had received stock advice from unreliable sources, and he faults the Government for failing to use a more "systematic" economic "event study" to tie the stock price movement to the alleged false statements. ECF No. 298, Tr. Vol. 14 at 203–04.

The jury, however, was correctly instructed on the materiality element. ECF No. 264 at 30. The jury also learned about the nature of the penny stock market of which CytoDyn was a part, including its relatively riskier investment posture. ECF No. 286, Tr. Vol. 2 at 67–68, 71. The jury further heard that the majority of CytoDyn investors were like the four witnesses in that they were mostly retail investors, not corporate entities. ECF No. 292, Tr. Vol. 8 at 41:13–21. Last, given that CytoDyn was a single drug, pre-revenue company, it is eminently logical that submission of a complete BLA or the chance to obtain an EUA was material to investors. *E.g.,* ECF No. 290, Tr. Vol. 6 at 165:4–16 (Munves testifying he reviewed the April 27 press release the day it was released and having a completed BLA was "key" because "[y]ou can't do anything unless you have a complete – a completed BLA. Otherwise, you can't get a BLA approval from FDA."); ECF No. 287, Tr. Vol. 3 at 181:24–182:5 (Horvath testifying "the press releases and the information produced by CytoDyn was, you know, my only view into the company and whether I should buy, sell, or hold on the stock itself."). Thus, the Court cannot grant judgment of acquittal on this basis.

The motions for judgment of acquittal are denied. The Court next turns to Defendants' motions for new trial.

IV. Motions for New Trial

Under Rule 33 the Court "should exercise its discretion to grant a new trial 'sparingly,' and . . . should do so 'only when the evidence weighs heavily against the verdict,'" *United States v. Perry*, 335 F.3d 316, 320 (4th Cir. 2003) (quoting *United States v. Wilson*, 118 F.3d 228, 237 (4th Cir. 1997)), or "when substantial prejudice has occurred," *United States v. Jones*, 542 F.2d 186, 211 (4th Cir. 1976). Unlike a Rule 29 motion, here the Court considers the credibility of the witnesses and assesses the evidence independently and holistically, "sitting as a thirteenth juror." *United States v. Rafiekian*, 68 F.4th 177, 186-87 (4th Cir. 2023) (quoting *Tibbs v. Fla.*, 457 U.S. 31, 43 n.18 (1982)). *See* WRIGHT & MILLER'S FEDERAL PRACTICE & PROCEDURE § 582 (cataloging the differences between the two standards). Where the jury's verdict is split, the Court may infer that the jury carefully considered the evidence against each defendant and based its verdict solely upon that evidence. *United States v. Cornell*, 780 F.3d 616, 627 (4th Cir. 2015) (citing *United States v. West*, 877 F.2d 281, 288 (4th Cir. 1989)). This inference, however, is not dispositive. The Court, as the thirteenth juror, may reweigh the evidence and "properly conclude that a new trial is warranted based on the cumulative weight of the evidence rather than by separately rejecting each individual offer of proof by the government." *Rafiekian*, 68 F.4th at 187 (internal citation omitted).

A. Kazempour

Kazempour advances three arguments for a new trial, two of which can be easily disposed. Kazempour contends that he should be retried because the Court erred in admitting a June 2021 email in which he tells members of Amarex's parent company, NSF, that Pourhassan had directed him to file the BLA "even if we are short." *See* GX 167. Kazempour explains in the email that the Amarex team had communicated to Pourhassan the "issues" with filing the BLA at that

juncture, and Pourhassan told Kazempour to "do it regardless!" *Id.* The Court admitted the document as a statement of a party opponent speaking directly to his knowledge and intent, having worked in concert to file the BLA "even if we are short." *Id.* Kazempour resurrects his objection from trial and now insists that its admission warrants a new trial. The Court disagrees.

Notably, unlike Pourhassan, Kazempour was acquitted of the substantive fraud count connected to the "even if short" email, so the jury did not ascribe it much weight as to him. But more to the point, it is relevant and highly probative of the Defendants' concerted activity to knowingly file a BLA that was likely to be rejected by the FDA. Given the overwhelming evidence reflecting Pourhassan's obsession with inflating the stock price and his communication of the same to Kazempour, the Court cannot credit that the email was "irrelevant" and unduly prejudicial warranting a new trial.

Kazempour also argues that this Court should grant a new trial because the Government's reference in closing to the FDA's opinion carrying more weight than other experts in the field on the efficacy of Leronlimab had been so prejudicial as to deprive Kazempour of a fair trial. The jury verdict says otherwise. *See* ECF No. 298, Tr. Vol. 14 at 170:2–172:12. Kazempour was acquitted of conspiracy and all fraud related to the COVID-19 trials. The Court also immediately gave the jury a curative instruction, reminding them that the FDA is to be accorded no special weight regarding its scientific opinions. ECF No. 298, Tr. Vol. 14 at 179:16–180:7. The jury presumptively followed these instructions. *See United States v. Zelaya*, 908 F.3d 920, 930 (4th Cir. 2018); *United States v. Johnson*, 587 F.3d 625, 633 (4th Cir. 2009). Defendants also presented ample evidence and testimony that called into question the soundness of the FDA's views on the efficacy of Leronlimab.[5] Thus, the Court will not award Kazempour a new trial on this basis.

[5] *E.g.,* testimony of Dr. Alice Chen (expert opining on validity of post hoc analyses). ECF No. 296, Tr. Vol. 12 at 19:5–24:23.

Kazempour's strongest argument, however, carries the day. Looking to the two counts of conviction—the April 27 BLA submission and his query about selling CytoDyn stock the next day—Kazempour contends that a joint trial with Pourhassan unfairly confused the jury and prejudiced Kazempour such that the jury likely convicted him on an insider trading theory, even though he had not been charged with insider trading. The Court agrees.

Insider trading is a form of securities fraud. *United States v. O'Hagan*, 521 U.S. 642, 652 (1997). But it is distinct from other liability theories of fraud which is why the Government charges insider trading separately. *See* Securities Exchange Act of 1934 § 10, 15 U.S.C. § 78j(b); *O'Hagan*, 521 U.S. at 652–53 (explaining the "traditional" and "classical" theories of insider trading). To convict a defendant of insider trading, the Government must prove beyond a reasonable doubt that the defendant (usually a corporate insider), who occupies a position of trust with the publicly traded company, bought or sold stock to his advantage based on the possession of material non-public information about the company. *O'Hagan*, 521 U.S. at 652 ("The classical theory [of insider trading] applies not only to officers, directors, and other permanent insiders of a corporation, but also to attorneys, accountants, consultants, and others who temporarily become fiduciaries of a corporation."). *See also United States v. Corbin*, 729 F. Supp. 2d 607, 613–14 (S.D.N.Y. 2010).

Particular to Kazempour, the Government acknowledged early on that it was not pursuing an insider trading case against him, only Pourhassan. *E.g.*, ECF No. 166 at 176, 196–97. And yet throughout the trial, the Government pressed the "insider trading" theory of guilt, inviting the confusion. In opening statement, the Government called Kazempour "an insider himself." ECF No. 286, Tr. Vol. 2 at 19:21, lumped Kazempour and Pourhassan together as both selling stock

"on their own lie," and emphasized the "money the defendants made" from deceiving the investor public, *id.* at 20:21–22. The Government promised the jury:

> You'll see from an FBI forensic accountant how *both defendants* sold their shares after the BLA announcement; Pourhassan immediately, even before any corrective statement had been issued, and Kazempour a little later, but not for lack of trying. And you'll see the money they made from this lie: 4.4 million for Pourhassan and more than 300,000 for Kazempour.

Id. at 20:10–15 (emphasis added).

Then—after having just referred to Kazempour as a CytoDyn "insider," the Government elicited from its first witness the following:

> Q. What are the limits to when an insider at a public company can sell stock in their own company?
>
> A. Insiders are not permitted to sell—buy or sell stock when they are—when they have what's known as material nonpublic information about a company—about their company.
>
> Q. And material nonpublic information, is that just any information that executives know or is it a specific category of information?
>
> A. Well, it's the type of information that a reasonable investor would find to be important when they are making their decision as to whether they are going to buy or sell the stock. It's a component where an investor would find it compelling when they're considering the total mix of information that's out there about the company.

Id. at 87:1–11.

The Government next put before the jury robust testimony supporting the Government's "insider" theory as to Kazempour. Former CytoDyn officer, Anthony Caracciolo, described Kazempour as CytoDyn's "regulatory officer," and one of the CytoDyn "staff" because he had been regularly involved in staff and board meetings. ECF No. 288, Tr. Vol 4 at 103:19, 44:1–9. CytoDyn's CFO, Mulholland, too referred to Kazempour as essentially the only "formally appointed agent" between CytoDyn and the FDA, causing CytoDyn to "place reliance on Dr.

Kazempour to have the best most current information available with respect to" the FDA. ECF No. 292, Tr. Vol. 8 at 71:15–23.

Then, in closing, the Government drove the point home. They called Kazempour a "member of the [CytoDyn] staff," ECF No. 298, Tr. Vol. 14 at 135:11–13, and that "[n]o one else had that level of access" into the company's goals of taking the drug to market and the FDA, *id.* at 135:19. The Government particularly stressed that Kazempour was "paid" in stock and so "if the stock price was to go up, he would profit from that." *Id*. at 136:1–6. And that "because of Dr. Kazempour's unique role in the company . . . he had that financial interest—in CytoDyn." *Id.* at 136:7–11. *See also id.* at 139:8–10 ("[E]ven though Dr. Kazempour is not part of the company, he's like part of the company.").[6] Indeed, the Government highlighted how "important" it is for the jury to "note" that Kazempour "sells [his stock] before the refuse-to-file is issued. He sells before the market becomes aware of the information that he knows, and his staff knows, which is that they don't have the thing that they need to make the BLA complete." *Id.* at 147:11–12. *See also id.* at 149:15–18 ("This really tells you all you need to know about [Kazempour's] intent. He's focused on selling his shares. And this is at a time when the *public still does not know* that the BLA is so incomplete that there will probably be filing issues.") (emphasis added).

Indeed, the confusion was compounded by the Government's choice to pursue a similar "insider" theory of liability against Kazempour on the securities fraud counts for which he was charged. *E.g.,* ECF No. 73 at 10:21–22 (Government acknowledging its "fox-in-the-henhouse" liability theory as to Kazempour); *id*. at 11:11–12 (Government counsel arguing that Kazempour sells his stock "while he's in possession of material, nonpublic information"). This is because

[6] The Government also emphasized that Kazempour's efforts to place stock in his wife's name was a badge of fraud because Kazempour had known at the time he filed the BLA it was not complete, and the consequent rise in stock price was his "motive" to participate in the conspiracy. ECF No 298, Tr. Vol. at 149:7–8.

Kazempour, as a contractor of CytoDyn, did not automatically possess the same fiduciary duties to CytoDyn as Pourhassan. Accordingly, the question of Kazempour's "duty" to correct false CytoDyn press releases or ensure that the releases were factually accurate had been a hotly contested matter throughout. *See id.*; *see also* ECF No. 197 at 192:2–199:23, 207:2–23. Nonetheless, the Government chose to press that liability theory (as opposed to the less controversial aiding and abetting theory) which is the Government's prerogative. But the Court cannot ignore how that choice likely led to significant confusion as to the basis on which Kazempour was convicted.

Perhaps the susceptibility for confusion is best captured by comparing insider trading instructions pertinent only for Pourhassan, and the securities fraud instructions for Kazempour. They are almost identical. For the non-insider trading counts, the jury was told that as to "duty" they must consider whether Kazempour "had a duty to CytoDyn shareholders to disclose material facts," to include whether he "had ***another position of trust or confidence*** within the corporation giving rise to such a duty. In this regard an officer or director of a corporation ***owes a special duty of trust and confidence to its shareholders***." ECF No. 264 at 30 (Jury Instruction No. 40) (emphasis added). *See also id.* at 31 (Jury Instruction No. 41 on the Duty to Correct a Material Fact). Likewise, for Pourhassan's insider trading counts, the jury was instructed, that "an insider is one who comes into possession of material, confidential, non-public information about a stock by virtue ***of a relationship that involves trust and confidence***." *Id.* at 67–68 (Jury Instruction No. 60) (emphasis added). Further, the jury was told that a person is "forbidden to buy or sell securities of a company if the Government establishes that ***he had assumed a special confidential relationship*** affording him access to material confidential information intended to be available only for a corporate purpose and not for his personal benefit." *See id.* at 68 (Jury Instruction No.

60) (emphasis added). This confusion could have been avoided were Kazempour and Pourhassan tried separately. The jury also would not have heard the robust evidence about insider trading as to Pourhassan which bore no relevance to the counts as to Kazempour. But because the Defendants were tried together, it is hard to imagine how the jury compartmentalized the strong evidence supporting the insider trading conviction of Pourhassan separate from Kazempour.

The risk that Kazempour's verdict suffered from unfair, prejudicial spillover is even greater when considering that the evidence against Kazempour was otherwise thin. Kazempour was acquitted of all other wrongdoing—conspiracy to commit securities and wire fraud writ large; the COVID-19 scheme; and even making false statements to the FBI agents about the number of shares he owned. Under these circumstances, the Court is deeply concerned that the jury mistakenly engrafted onto Kazempour the "insider trading" theory and evidence meant only for Pourhassan.

The Government responds with valid points. Most persuasively, they argue that a jury, especially one that deliberated for five days and issued split verdicts as to both Defendants, is presumed to have followed the Court's instruction and delivered a constitutionally sound verdict. ECF No. 371 at 17. The Government equally emphasizes that a jury verdict remains inviolate and to be overturned only in the most extraordinary of circumstances. *Id.* at 7. The Court agrees with these fundamental principles. But they do not eclipse the unfairness in allowing Kazempour's verdict to stand.[7] Because of this, the Court concludes that Kazempour is entitled to a new trial on Counts 3 and 8 so that the jury may fairly assess the weight of the evidence against Kazempour free of prejudicial spillover.

[7] The Government also wrongly argues that Kazempour did not raise during pretrial the likelihood of prejudicial spillover from Pourhassan's insider trading charges. ECF No. 371 at 27. He did. ECF No. 61 at 6, 10, 15. *See also* ECF No. 166 at 196 (raising confusing question of insider "duty" as to Kazempour when he is not charged with insider trading). In fact, the Court entertained extensive argument on the confusion animating the Government's charging choices on the question of duty, particularly on the multiple alternate liability theories it could have pursued against Kazempour. ECF No. 166 at 202–04; *see also id.* 204:19–20 (Government admitting that "duty is one of the *three* ways in which we can prove the substantive securities fraud count" as to Kazempour).

B. Pourhassan's Motion for New Trial

Pourhassan essentially filed *two* motions for new trial. In the first, he urges that for the same reasons he was entitled to judgment of acquittal, he should receive a new trial. ECF No. 312-1 at 35–36. The Court rejects those arguments for the same reasons already discussed.

After a hearing on these motions, Pourhassan sought leave to supplement his Rule 33 motion to address exclusively that if the Court grants Kazempour a new trial, Pourhassan ought in fairness receive a do-over as well. The Court also rejects that argument for the following reasons.

Pourhassan primarily argues that he should be awarded a new trial because he would have made different strategic decisions had he stood trial alone. Chief among them is that he "may well have" testified in his own defense. ECF No. 370 at 3. This bald, self-serving proposition is a non-starter. Unlike Kazempour, the evidence against Pourhassan was substantial. Without a particularized showing as to how Pourhassan's right to testify was not only encumbered but prejudicially so, a new trial is not warranted.

Pourhassan next contends that Kazempour acted as a "second prosecutor" by shifting the blame away from himself and onto Pourhassan. ECF No. 370 at 3. As a matter of law, antagonistic defenses alone do not warrant severance, and by extension, do not support a new trial. *See Dinkins*, 691 F.3d at 369 ("Hostility among defendants, and even a defendant's desire to exculpate himself by inculpating others, do not of themselves qualify as sufficient grounds to require separate trials."). But even if it did, the defenses here were simply not antagonistic. Sure, Pourhassan blamed Amarex, and Kazempour as the regulatory expert, for misadvising him about the status of the BLA and the efficacy of Leronlimab as to COVID-19. ECF No. 286, Tr. Vol. 2 at 30:23–31:12, 35:20–23 (opening statement); ECF No. 287, Tr. Vol 3 at 106 (cross of Kimberly Struble, FDA witness); ECF No. 295, Tr. Vol. 11 at 22 (direct of Dr. Mark Robbins, defense regulatory expert). Defense expert, Dr. Mark Robbins, particularly discussed why companies like CytoDyn

rely on companies like Amarex for specific knowledge and expertise. ECF No. 295, Tr. Vol. 11 at 31:9–16 (Q: Dr. Robbins, do pharmaceutical companies navigate the drug development process alone? A: No. Pharmaceutical companies always use experts that help navigate the process. . . . With small pharmaceutical companies, you're much more dependent upon getting outside resources."). *See also id.* at 32–35. He also emphasized why regulatory agents such as Kazempour are essential to the licensing process in that they are the subject matter experts in shepherding the company through FDA licensure. *Id.* at 35–45. In closing, Pourhassan focused the jury on this theory: Pourhassan "relied on the experts that he hired and held accountable for their advice." ECF No. 298, Tr. Vol. 14 at 181:7–9.

Kazempour's defense, by contrast, emphasized that neither he nor Pourhassan were guilty of fraud at all. *E.g.*, ECF No. 298, Tr. Vol. 14 at 233:5–7 (arguing that the April 14 email from Pourhassan triggered Amarex to "work really hard to finish" the BLA); *id.* at 233:13–17 (Amarex employees testifying they didn't think there was "anything wrong" with submitting the BLA absent reformatted datasets); *id.* at 237:4–5 (Kazempour arguing "whatever you think about" the April 27 BLA, "it had been fixed by May 11th"). Kazempour also stressed an equally Pourhassan-friendly theme that the FDA reviewers were deeply biased against CytoDyn and so were never going to approve Leronlimab as a therapeutic. *Id.* at 238:7–9. Pourhassan further benefitted from Kazempour's expert witness who opined that Leronlimab helped some patients even if the primary endpoints of the trials had not been met. *See* ECF No. 296, Tr. Vol 12 at 15 (testimony of expert Dr. Alice Chen). *See also* ECF No. 298, Tr. Vol. 14 at 243:6–7 ("Alice Chen told you that, when the FDA said that the COVID-19 clinical trials showed no benefit, the FDA was wrong."). Thus, Pourhassan's "second prosecutor" theory bears little relationship to what happened at trial.

In the end, the asymmetry of evidence—strong as to Pourhassan, far less so to Kazempour—combined with the Government's prosecutorial choices, rendered the trial fundamentally unfair as to one but not the other. Pourhassan's new trial motion is DENIED.

IV. Conclusion

For the reasons stated above, Defendant Kazem Kazempour's motion for judgment of acquittal is DENIED but his motion for new trial is GRANTED. Defendant Nader Pourhassan's motions for acquittal and new trial are DENIED. A separate Order follows.

Date: January 16, 2026

/s/
PAULA XINIS
United States District Judge