ASJZ/LJW: USAO#2021R00610

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
	*	**UNDER SEAL**
v.	*	
	*	**CRIMINAL NO.** PX 22cr440
NADER POURHASSAN, and	*	
KAZEM KAZEMPOUR,	*	**(Conspiracy, 18 U.S.C. § 371;**
	*	**Securities Fraud, 15 U.S.C. §§ 78j(b),**
Defendants.	*	**78ff and 17 C.F.R. § 240.10b-5; Wire**
	*	**Fraud, 18 U.S.C. § 1343; False**
	*	**Statements to Federal Law**
	*	**Enforcement, 18 U.S.C. § 1001;**
	*	**18 U.S.C. §§ 981(a)(1)(C))**
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INDICTMENT

The Grand Jury for the District of Maryland charges:

COUNT 1
(18 U.S.C. § 371 – Conspiracy to Commit Offenses Against the United States)

At all times relevant to this Indictment, unless otherwise stated:

Relevant Individuals and Entities

1. Defendant **NADER POURHASSAN** resided in Lake Oswego, Oregon, and served as the President and Chief Executive Officer of CytoDyn Inc. ("CytoDyn").

2. CytoDyn was a publicly traded late-stage biotechnology company with offices in Vancouver, Washington. CytoDyn's common stock traded over the counter, and shares were available for purchase and sale by the public. CytoDyn's shareholders lived throughout the United States and around the world, including in the District of Maryland. CytoDyn issued and caused to be issued press releases that were posted on CytoDyn's Internet website and distributed across the Internet via Media Company 1.

3. CytoDyn focused on the clinical development and potential commercialization of leronlimab (PRO 140), a monoclonal antibody investigational drug. For over a decade, CytoDyn investigated and developed leronlimab as a potential treatment for human immunodeficiency virus ("HIV") and COVID-19, among other diseases. Leronlimab has never been approved by the FDA to be marketed and used for the treatment of any disease.

4. Since its inception, CytoDyn incurred operating losses each year due to the costs of research and development and lack of any revenue. CytoDyn therefore required a significant amount of capital to continue the investigation and attempted development of leronlimab. From in or around 2018 to in or around 2021, **POURHASSAN** worked aggressively to finance CytoDyn's cash needs by selling equity and debt securities. During this time, **POURHASSAN** was preoccupied with the price of CytoDyn's publicly traded common stock, which informed the price at which CytoDyn potentially could offer new securities. Between in or around 2018 and in or around 2021, **POURHASSAN** raised more than $200 million by selling equity and debt securities.

5. Defendant **KAZEM KAZEMPOUR** resided in the District of Maryland. **KAZEMPOUR** founded Amarex Clinical Research LLC ("Amarex") in 1998 and served as its Chief Executive Officer since that time. In addition, beginning in or around 2018, **KAZEMPOUR** became a member of CytoDyn's Disclosure Committee, which was responsible for reviewing and approving CytoDyn's periodic reports filed with the U.S. Securities and Exchange Commission ("SEC"), including CytoDyn's quarterly reports on Form 10-Q and annual reports on Form 10-K.

6. Amarex was a private company with offices in Germantown, Maryland. Amarex functioned as a contract research organization ("CRO"), managing clinical trials and serving as the regulatory agent for its clients, including CytoDyn, with the U.S. Food and Drug

Administration ("FDA"). In its role as CytoDyn's regulatory agent, Amarex communicated with the FDA on CytoDyn's behalf. Amarex managed numerous clinical trials for CytoDyn beginning in or around 2014 and continuing through in or around 2021.

7. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human drugs, among other products. The FDA does not itself develop or test products. Rather, the FDA reviews the results of laboratory, animal, and human clinical testing done by companies to determine whether any product that companies propose to market is safe and effective. The FDA does this premarket review for new human drugs and biologics, among other products. A company requesting permission to introduce a biologic product into interstate commerce must submit a Biologics License Application ("BLA") with the FDA.

8. In or around 2018, CytoDyn, together with its regulatory agent, Amarex, began to prepare to submit a BLA for leronlimab as a potential treatment for HIV to the FDA. Throughout 2018, 2019, and 2020, **POURHASSAN**, **KAZEMPOUR**, and other representatives from CytoDyn and Amarex met regularly with the FDA to discuss the BLA review process, including the timeline and requirements for the BLA. The FDA explicitly instructed **POURHASSAN**, **KAZEMPOUR**, CytoDyn, and Amarex on the requirements necessary to complete the BLA submission and warned that each required component of the BLA submission had to be complete when submitted in order for the FDA to begin its review. For example:

a. On or about June 18, 2018, **POURHASSAN**, **KAZEMPOUR**, and other representatives from CytoDyn and Amarex met with the FDA to discuss the BLA. The meeting minutes, which were prepared by the FDA and shared with CytoDyn and Amarex, stated:

> The content of a complete application was discussed . . . . FDA advised CytoDyn of initial findings and concerns with the data to

> support a BLA approval and restated the review issues which could affect approvability and the need for an advisory committee meeting. CytoDyn stated their confidence in the robustness of the efficacy data regardless of how missing data is handled or analysis methods. In addition, FDA informed CytoDyn that the process validation and full [process, performance and qualification] information will need to be completed and included with the BLA, no late components would be accepted.

b. On or about December 14, 2018, **POURHASSAN**, **KAZEMPOUR**, and other representatives from CytoDyn and Amarex, again met with the FDA. The stated purpose of the meeting was "for FDA to outline specific and potential 'Refuse to File' issues to allow for CytoDyn to address findings in advance of a planned BLA submission for PRO 140." The FDA reiterated that the BLA submission had to be complete and explained that an incomplete BLA would be a "Definite Refuse to File Issue[.]" The meeting minutes, which were prepared by the FDA and shared with CytoDyn and Amarex, stated:

> **Advice on Filing Requirements / Definite Refuse to File Issues**
>
> Although not the focus of this meeting, FDA briefly reiterated the previous advice provided to CytoDyn regarding outstanding information that needs to be completed prior to submission of a BLA, where if not submitted in completed form, would be considered Refuse to File issues. These include: final [chemistry, manufacturing and controls] information . . . .

9. Around the same time, the FDA also repeatedly expressed concerns to CytoDyn and Amarex about the companies' proposed timeline for submitting the BLA, which **POURHASSAN** had selected and **KAZEMPOUR** had conveyed to the FDA. The FDA repeatedly cautioned that CytoDyn and Amarex should slow down to ensure a complete submission that contained all information necessary for the FDA to begin its review. For example, on or about December 28, 2018, a representative of the FDA sent an e-mail to **KAZEMPOUR**, as

a representative of CytoDyn's regulatory agent, to express concerns about CytoDyn's proposed timeline for the submission of the BLA:

> [W]e are concerned that you are operating on an overly optimistic timeline for your BLA submission. You have requested that we allow amendments to your ongoing trials so that you can collect at least 12 weeks of safety data from at least 100 subjects receiving the 700 [milligram (mg)] SQ weekly dose of PRO 140. We are concerned that you expect to submit the data collected from these additional subjects by the end of March 2019. Even if these amendments were to be approved instantaneously and you were to enroll all 60 additional subjects immediately, you would be left with less than a month to review and analyze the efficacy and safety data. Because the data you submit in your BLA submission must be accurate, clear, and well-organized for BLA review and Advisory Committee preparation, we wanted to raise your awareness that you will be putting your BLA at risk by rushing your BLA submission.

On or about January 3, 2019, **KAZEMPOUR** sent a written response acknowledging the FDA's concerns about CytoDyn's "rush[ed]" timeline. Also among the list of the FDA's concerns was a "reminder" for CytoDyn "to submit mock datasets prior to BLA submission so any problems with compatibility can be resolved prior to BLA submission."

10. The SEC is an agency within the executive branch of the federal government that is responsible for regulating the securities markets, including the issuance, marketing, and trading of securities. CytoDyn's securities were regulated by the SEC. Public companies, like CytoDyn, provide information to the SEC and investors by filing certain SEC Forms with the SEC using the agency's Electronic Data Gathering, Analysis, and Retrieval ("EDGAR") system. EDGAR is a database available to investors and the general public via the Internet throughout the United States, including in the District of Maryland.

The Conspiracy to Execute the Schemes to Defraud

11. Beginning at least in or around 2018 and continuing through at least in or around 2021, in the District of Maryland and elsewhere, the defendants,

NADER POURHASSAN

and
KAZEM KAZEMPOUR,

knowingly and willfully conspired with each other and others known and unknown to the grand jury to commit certain offenses against the United States, namely:

a. securities fraud, that is, to knowingly and willfully, directly and indirectly, by use of the means and instrumentalities of interstate commerce, and of the mails, in connection with the purchase and sale of securities, use and employ, and cause others to use and employ, manipulative and deceptive devices and contrivances, in violation of Title 17, Code of Federal Regulations, Section 240.10b-5 by: (a) employing, and causing others to employ, devices, schemes, and artifices to defraud; (b) making, and causing others to make, untrue statements of material fact and omitting to state, and causing others to omit to state, material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; and (c) engaging, and causing others to engage, in acts, practices, and courses of business which operated and would operate as a fraud and deceit upon persons, to wit: to defraud investors in CytoDyn through materially false and misleading representations and material omissions relating to CytoDyn's investigation and attempted development of leronlimab as a potential treatment for HIV, including the timeline and status of CytoDyn's regulatory submissions to, and review of leronlimab by, the FDA, in violation of Title 15, United States Code, Sections 78j and 78ff, Title 17, Code of Federal Regulations, Section 240.10b-5, and Title 18, United States Code, Section 2; and

b. wire fraud, that is, to knowingly and with the intent to defraud, devise and intend to devise a scheme and artifice to defraud and for obtaining money and property by means

of materially false and fraudulent pretenses, representations and promises, knowing that the pretenses, representations and promises were false and fraudulent when made, and did knowingly transmit and cause to be transmitted, by means of wire communications, writings and signals in interstate and foreign commerce certain writings, signs, signals, pictures and sounds, for the purpose of executing such scheme or artifice, to wit: to defraud investors in CytoDyn through materially false and misleading representations relating to CytoDyn's investigation and attempted development of leronlimab as a potential treatment for HIV, including the timeline and status of CytoDyn's regulatory submissions to, and review of leronlimab by, the FDA, in violation of Title 18, United States Code, Section 1343.

PURPOSE OF THE CONSPIRACY AND SCHEMES TO COMMIT FRAUD

12. It was the purpose of the conspiracy and the schemes to defraud for the defendants to unjustly enrich themselves by: (i) making materially false and misleading representations to investors relating to CytoDyn's investigation and attempted development of leronlimab as a potential treatment for HIV, including the timeline and status of CytoDyn's regulatory submissions to, and review of leronlimab by, the FDA; (ii) concealing from investors the true facts; (iii) diverting the proceeds of the scheme and artifice for their personal use and benefit, including

through the issuance and exercise of stock options and the sale and attempted sale of CytoDyn stock; and (iv) concealing the scheme from regulators, law enforcement, investors, and the media.

MANNER AND MEANS OF THE CONSPIRACY AND SCHEMES TO DEFRAUD

The manner and means by which the defendants sought to accomplish the purpose of the conspiracy and the schemes included, but were not limited to, the following:

13. **POURHASSAN** marginalized and later removed from CytoDyn's Board certain directors who attempted to exercise oversight of **POURHASSAN**'s public statements, including press releases drafted by **POURHASSAN**. **POURHASSAN** also marginalized and terminated the employment of CytoDyn employees who expressed concerns that **POURHASSAN**'s public statements were potentially false and misleading.

14. **POURHASSAN** and **KAZEMPOUR** repeatedly made, and caused CytoDyn to make, materially false and misleading representations about the timelines by which CytoDyn and Amarex would complete and submit CytoDyn's BLA for leronlimab as a potential treatment for HIV to the FDA. These timelines were not based on whether CytoDyn and Amarex could meet the FDA's requirements for a BLA, and instead were based on what **POURHASSAN** believed would inflate and maintain CytoDyn's stock price and attract new investors. CytoDyn directors and executives, Amarex executives, and the FDA repeatedly warned **POURHASSAN** and **KAZEMPOUR** that **POURHASSAN**'s timelines for submitting the BLA could not be met. **POURHASSAN** nevertheless continued to publicly tout the timelines he had selected. Consistent with these warnings, CytoDyn and Amarex repeatedly failed to submit the BLA within the timelines **POURHASSAN** had publicly announced.

15. In April 2020, after CytoDyn and Amarex repeatedly missed publicized timelines, **POURHASSAN** directed **KAZEMPOUR** and Amarex to submit the BLA to the FDA even if it

was "short" – *i.e.*, incomplete – so that he could announce to investors that it had been submitted. **POURHASSAN** and **KAZEMPOUR** knew that the FDA would refuse to review an incomplete BLA. **KAZEMPOUR** and Amarex did, in fact, submit an incomplete BLA, which the FDA refused to file, as expected.

16. In order to artificially inflate and maintain CytoDyn's stock price and attract new investors, **POURHASSAN** and CytoDyn misrepresented in a press release that a "complete" BLA had been submitted to the FDA on April 27, 2020. In truth and in fact, a complete BLA had not been submitted.

17. After the FDA informed **KAZEMPOUR**, who in turn directed Amarex Executive 1 to inform **POURHASSAN,** that the BLA was incomplete and the April 27, 2020 press release stating the opposite was misleading, **POURHASSAN** and **KAZEMPOUR** failed to correct the false and misleading April 27, 2020 press release.

18. Further, even after the FDA informed **KAZEMPOUR**, who directed Amarex Executive 1 to inform **POURHASSAN,** that the BLA was incomplete, **POURHASSAN** made additional false and misleading statements that a complete BLA would be submitted and, later, that a completed BLA had been submitted, all while knowing that CytoDyn did not possess the necessary data to complete the BLA.

19. **POURHASSAN** made and caused to be made these materially false and misleading representations in, and omitted material information from, CytoDyn press releases, SEC filings, interviews he distributed on the Internet, and in print and online media, all of which were intended to reach, and did in fact reach, investors and the general public throughout the United States, including within the District of Maryland. **POURHASSAN** arranged the media appearances and authored, reviewed, approved, issued, and disseminated the press releases and SEC filings.

POURHASSAN and CytoDyn posted the press releases on CytoDyn's website and disseminated the press releases across the Internet via Media Company 1.

20. To conceal the conspiracy and schemes from regulators, law enforcement, investors, and the media, **POURHASSAN** used CytoDyn funds to arrange interviews in which he directly responded to and sought to refute allegations that **POURHASSAN** had engaged in fraud or wrongdoing, and similarly used CytoDyn funds to pay stock promoters to respond to **POURHASSAN**'s critics in online forums.

21. To conceal the conspiracy and schemes from law enforcement, **KAZEMPOUR** made materially false statements to federal agents regarding his ownership of CytoDyn stock.

OVERT ACTS IN FURTHERANCE OF THE CONSPIRACY AND SCHEMES TO DEFRAUD

22. In furtherance of the conspiracy and to accomplish its objects, the following overt acts were committed in the District of Maryland, and elsewhere:

POURHASSAN Eliminated CytoDyn Directors and Executives Who Expressed Concern About the Accuracy and Truthfulness of His Public Representations

23. Certain members of CytoDyn's Board of Directors, including Director 1 and Director 2, expressed concerns about **POURHASSAN**'s preoccupation with CytoDyn's stock price and **POURHASSAN**'s inaccurate and exaggerated public representations regarding leronlimab's development. In or around 2017, Director 1, who was then CytoDyn's Chairman, attempted to institute safeguards to ensure the accuracy and truthfulness of **POURHASSAN**'s public representations, including in CytoDyn press releases. **POURHASSAN** rejected the Board's oversight, complaining that it unnecessarily limited his ability to raise new money from investors. In or around 2018, **POURHASSAN** orchestrated Director 1's replacement as Chairman with

POURHASSAN's own hand-picked candidate. **POURHASSAN** then pushed Director 1 off CytoDyn's Board.

24. Beginning in or around 2018, **POURHASSAN** caused CytoDyn's Board to effectively cease meaningful oversight of **POURHASSAN**'s public representations. In an e-mail to a CytoDyn vendor on or about December 7, 2018, **POURHASSAN** described how when Director 1 "stepped down," **POURHASSAN** "immediately raised about $19 million."

25. On or about March 16, 2019, **POURHASSAN** updated CytoDyn's Board about his efforts to boost the company's stock price, including by using videotaped interviews of himself to attract new investors:

> [T]he key to higher stock price without reverse split and up-listing is HIGHER VOLUME. If we generate higher volume, we will wash through all the shares that need to be traded to new hands and stock will then see much higher levels (we had orchestrated that in past, 2014 to 2016 and we believe we can do it again).
>
> We now have the right IR firm … and will have great plan of attack the problems we faced. Along with [the IR firm's] efforts we are having continuous campaign of video interviews .... Radio interviews and TV campaign that just started yesterday …

26. Director 2 remained on CytoDyn's Board through the first half of 2019. During that time, Director 2 continued to challenge **POURHASSAN** on his public representations regarding leronlimab's development. In or around July 2019, **POURHASSAN** orchestrated Director 2's removal from the Board. In or around December 2019, after removing from the Board multiple directors who had attempted to institute safeguards over his public representations, **POURHASSAN** caused the award of hundreds of thousands of stock options to remaining directors and other individuals whom he viewed as allies.

27. **POURHASSAN** also marginalized and terminated CytoDyn executives who expressed concern regarding the accuracy and truthfulness of **POURHASSAN**'s representations

regarding leronlimab's development. For example, from in or around December 2020 to in or around March 2021, CytoDyn Executive 1 repeatedly expressed concerns regarding representations **POURHASSAN** and CytoDyn made to the FDA, and to the public in press releases, regarding leronlimab's efficacy in treating COVID-19 based on flawed analyses of clinical data for patient subpopulations. In or around mid-March 2021, **POURHASSAN** eliminated CytoDyn Executive 1's role as part of the review process for CytoDyn press releases. On or about April 5, 2021, **POURHASSAN** terminated CytoDyn Executive 1's employment.

POURHASSAN Made Materially False and Misleading Representations About the Timelines for Submission of a BLA for Leronlimab

28. On or about November 13, 2018, **POURHASSAN** and CytoDyn issued a press release titled "PRO 140 (leronlimab) HIV Monotherapy Trial Results Show 92% Responder's Rate at 700mg Dose." The press release stated that "CytoDyn remains on track to complete its filing of a biologics license application (BLA) for PRO 140 . . . with the FDA by the first quarter of 2019." **POURHASSAN**'s and CytoDyn's representations in this press release were materially false and misleading, and omitted material information, because, in truth and in fact, and as **POURHASSAN** knew, CytoDyn was not on track to submit a complete BLA to the FDA on the stated timeline. In fact, **POURHASSAN** had selected the timeline for the BLA's submission based on what he believed would inflate and maintain the price of CytoDyn stock and raise new money from investors and not on whether CytoDyn could meet the FDA requirements by the first quarter of 2019.

29. On or about February 1, 2019, after interim data from CytoDyn's HIV monotherapy clinical trials supported changing from a 350mg dose to a 700mg dose of leronlimab for HIV patients, **POURHASSAN** and CytoDyn issued a press release announcing the new focus on the 700mg dose and stating that the FDA had agreed to an approach that would "avoid a long delay in

the BLA filing[.]" **POURHASSAN** also was quoted as stating: "We believe we can realize significant revenue opportunities by 2020 assuming the first approval of leronlimab[.]" **POURHASSAN**'s and CytoDyn's representations in this press release were materially false and misleading because they omitted the significance of the dosage change, which was, among other things, that substantial additional work and data were required to justify the new dose, and continued to advance the materially false and misleading narrative that the BLA would be submitted quickly. In or around January 2019, **POURHASSAN**, **KAZEMPOUR**, and other representatives from CytoDyn and Amarex had discussed the 700mg dosage data with FDA. The FDA recommended that the BLA focus on the 700mg dosage. In doing so, the FDA agreed to accept certain safety data from the ongoing monotherapy trial in connection with the BLA, but communicated to **POURHASSAN**, **KAZEMPOUR**, and other representatives from CytoDyn and Amarex that additional dose justification data would be required. The additional data needed to support the 700mg dosage required substantial additional work.

30. In 2019 and 2020, **POURHASSAN**'s communications repeatedly emphasized the link between the BLA timeline and CytoDyn's stock price or the ability to raise money from new investors. For example, on or about February 7, 2019, in an e-mail that **POURHASSAN** later forwarded to CytoDyn's Board, he wrote, "if this shipment [of leronlimab] is not proceed [sic], we will have another set back in our BLA timeline. This could paralyze our company from raising future funds and will not be good for any of us."

31. After the first-quarter 2019 BLA timeline passed, **POURHASSAN** and CytoDyn announced in a press release on or about March 18, 2019, that the "first of three sections of the BLA submission" had been filed with the FDA. The press release further stated that "[t]his is the most important milestone yet in CytoDyn's history," and "[w]e continue to execute on the

submission of our BLA and are well positioned for potential revenue in 2020, subject to final approval." **POURHASSAN** and CytoDyn's representations in this press release were materially false and misleading because, in light of the work that remained to be done on the BLA submission, CytoDyn would not be able to generate revenue from the commercialization of leronlimab in 2020.

32. During 2019 and early 2020, **POURHASSAN** publicly announced additional timelines for completing the BLA submission—timelines he knew were unachievable—to raise new money from investors. **POURHASSAN** knew these statements were misleading investors. For example, in an e-mail to a CytoDyn vendor on or about January 23, 2020, **POURHASSAN** wrote, "We will be getting many lawsuits from our shareholders if we can't deliver the BLA section of our [Chemistry, Manufacturing and Controls] [sic]."

33. In written communications between in or around February 2020 and in or around April 2020, including communications with **KAZEMPOUR**, **POURHASSAN** explicitly stated that it was necessary to submit the BLA to increase and maintain CytoDyn's stock price. For example, on or about February 8, 2020, in an electronic message to **KAZEMPOUR** and Amarex Executive 1, **POURHASSAN**, wrote, "We told the public on Thursday that the BLA is delayed until the end of February and on Thursday and Friday our stock dropped and our market cap went down by $200 million and everyone is asking for my head[.] If we can't get BLA done by the end of February we will have another tremendous drop in our stock[.]"

34. On or about April 6, 2020, **POURHASSAN** wrote in an e-mail to CytoDyn Executive 2, copying Amarex Executive 1, "Please let me know if we can file both sections of BLA (CMC and Clinical) no later than April 15 and if we do what will we be risking?" **POURHASSAN** knew at that time, because the FDA had made it clear, that submitting an incomplete BLA would result in a "definite" refusal to file by the FDA.

35. On or about April 9, 2020, CytoDyn submitted its quarterly SEC filing on SEC Form 10-Q, which was publicly available via the Internet to investors throughout the United States, including in the District of Maryland. **POURHASSAN** reviewed, approved, and signed this filing. CytoDyn's 10-Q filing stated, "We expect to submit the remaining two sections of the BLA in the [sic] April of 2020." CytoDyn's 10-Q filing was materially false and misleading because, in truth and in fact, **POURHASSAN**, **KAZEMPOUR**, CytoDyn, and Amarex knew that data and information required by the FDA was not available to submit by the end of April 2020 and, therefore, the remaining two sections of the BLA could not be submitted on that timeline.

POURHASSAN and KAZEMPOUR Submitted an Incomplete BLA for Leronlimab In Order to Increase CytoDyn's Stock Price

36. On or about April 12, 2020, **POURHASSAN** sent an electronic message to CytoDyn Executive 2 in which he stated:

> I just had another long talk with [Amarex Executive 1.] Afterwards I have been taking to several of our shareholders[.] We could do a very large fund raising of $100 million and these guys are ready now but I need to do this after BLA submission to give our stock the best chance for this very large raise[.] Please shoot for April 15 submission if possible without dangering [sic] anything and if at the end we need a few more days then so be it[.]

37. Two days later, on or about April 14, 2020, **POURHASSAN**, sent an e-mail to **KAZEMPOUR** and Amarex Executive 1, copying CytoDyn Executive 2. In the e-mail, **POURHASSAN** explicitly instructed **KAZEMPOUR** and Amarex Executive 1 that the BLA should be filed even if it was "short" (*i.e.*, incomplete):

> Today we have so far in 1 hour almost 20% drop in our stock price. Yesterday we had drop [sic] also after putting out great results about COVID-19 patients we are seeing these [sic] type of decline. This drop will be much deeper if we don't file our BLA as the message board now is getting bombarded by investors who are very frustrated with me and CytoDyn. Please 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.

POURHASSAN emphasized that "if [CytoDyn's] stock continues its drift then financially we will have problems financing itself [sic]. THE MOST IMPORTANT thing now is BLA. . . ."

38. On or about April 27, 2020, **KAZEMPOUR** and Amarex filed an incomplete BLA on CytoDyn's behalf. The cover letter accompanying the submission, which **KAZEMPOUR** signed, acknowledged that the submission did not include clinical datasets that FDA had repeatedly told **POURHASSAN**, **KAZEMPOUR**, CytoDyn, and Amarex were required for the FDA to begin its review. **POURHASSAN**, **KAZEMPOUR**, CytoDyn, and Amarex knew that the BLA submission was incomplete and would result in a "definite" refusal to file as the FDA had repeatedly warned in meetings attended by **POURHASSAN**, **KAZEMPOUR**, and other representatives of CytoDyn and Amarex. The BLA submission was a deceptive device that **POURHASSAN** directed and **KAZEMPOUR** carried out for the purpose of allowing **POURHASSAN** and CytoDyn to mislead investors and the public by misrepresenting that the BLA was submitted and would therefore be reviewed by the FDA. In truth and in fact, and as **POURHASSAN**, **KAZEMPOUR**, CytoDyn, and Amarex knew, the FDA would reject the submission as incomplete.

39. Also on or about April 27, 2020, **POURHASSAN** and CytoDyn issued a press release titled "CytoDyn Submits Completed Biologics License Application to the FDA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients." The press release specifically quoted **POURHASSAN** as saying, "With the BLA filing for a combination therapy now complete . . . ." **POURHASSAN**'s and CytoDyn's representations in this press release were materially false and misleading. In truth and in fact, and as **POURHASSAN** and CytoDyn knew, the BLA submission was not complete because it lacked clinical datasets and other information that were required for FDA to conduct its review.

KAZEMPOUR and Amarex had only submitted the BLA so that **POURHASSAN** and CytoDyn could misleadingly announce it had been submitted, while omitting the material information that the BLA was incomplete and would be rejected by the FDA.

40. On or about April 27, 2020, **POURHASSAN** and CytoDyn held an investor conference call, which was disseminated via the Internet to investors throughout the United States, including in the District of Maryland. During the call, **POURHASSAN** repeated materially false and misleading representations that CytoDyn had submitted the BLA to the FDA. For example, **POURHASSAN** stated that the "BLA timeline was pushed back constantly," but falsely and misleadingly claimed that "these pushbacks were all due to CytoDyn's success," describing the change to the higher, 700mg dose and work on COVID-19 clinical trials. In truth and in fact, as **POURHASSAN** knew, the failure to meet the timelines was due to **POURHASSAN**'s selection of the timelines based on what he believed would inflate and maintain CytoDyn's stock price and raise new money from investors, rather than basing the timelines on whether CytoDyn and Amarex could meet the FDA's requirements for a BLA. **POURHASSAN** also stated, "So in short…the BLA is submitted," while omitting the material information that the BLA was incomplete and would be rejected by the FDA.

41. On or about April 28, 2020, the day after CytoDyn issued its false and misleading press release about the BLA submission, **KAZEMPOUR** sent an e-mail to CytoDyn Executive 3, copying **POURHASSAN** and **KAZEMPOUR**'s financial advisor, about selling shares of CytoDyn stock: "Several years ago, Board of CytoDyn [sic] gave me 150,000 share options, and after this many years, I am thinking to sell the shares now!! I talked to my brokerage [agent] (CCed here), and he told me to communicate with you and CC him so you can explain to me/him what we need to do to sell those shares."

POURHASSAN and KAZEMPOUR Failed to Correct the False and Misleading April 27, 2020, Press Release

42. On or about April 30, 2020, **KAZEMPOUR** forwarded an email from the FDA, dated on or about April 29, 2020, to Amarex Executive 1, who in turn forwarded the FDA's e-mail to **POURHASSAN**. The FDA's April 29, 2020, e-mail had informed **KAZEMPOUR** that the BLA was not complete and that CytoDyn's April 27, 2020, press release contained misinformation. The FDA's e-mail stated, in pertinent part:

> We have communicated to you on multiple occasions . . . whereby we clarified that the BLA review clock does not begin until the applicant informs the Agency that a complete BLA was submitted.
>
> Your April 27, 2020, submissions do not constitute a completed BLA as CytoDyn has reported to the public via press release.
>
> The BLA application is not considered complete as you yourself acknowledged in your covering letter with the April 27, 2020, submission – noting that the clinical datasets remain outstanding.
>
> As the regulatory agent on behalf of CytoDyn our expectation is that you have communicated this information to CytoDyn. We ask you to take regulatory responsibility for the misinformation released in the aforementioned Press Release by notifying CytoDyn.
>
> Further we ask that you formally retract submission of the clinical module and resubmit at such a time when this module is considered fully complete. We had not made any prior agreements that an incomplete clinical module could be submitted (missing datasets).

Despite the admonishment that the FDA did not consider the BLA to be complete and would not begin reviewing the submission, and the warning from the FDA about the "misinformation" in CytoDyn's April 27, 2020, press release, neither **POURHASSAN** nor **KAZEMPOUR**, who were on CytoDyn's Disclosure Committee, corrected the materially false and misleading representations that the BLA would be and had been completed and submitted in April 2020. Given their roles

and their receipt of the FDA's admonishments, both **POURHASSAN** and **KAZEMPOUR** had a duty to correct these representations.

43. Upon the submission of the BLA, pursuant to an award of stock options by CytoDyn's Board in or around December 2019, hundreds of thousands of CytoDyn stock options for multiple CytoDyn directors and executives, including **POURHASSAN**, vested and were available to exercise. The vesting event was merely the submission of the BLA and did not require that the BLA was complete or was accepted for review by the FDA. Beginning on or about April 30, 2020, **POURHASSAN** exercised stock options and sold millions of shares of CytoDyn stock in the following approximate amounts:

a. On or about April 30, 2020 – 2.2 million shares valued at $7.8 million.

b. On or about May 1, 2020 – 1.39 million shares valued at $4.5 million.

c. On or about May 4, 2020 – 1.2 million shares valued at $3.3 million.

POURHASSAN engaged in those trades while in possession of material information not known to the public, namely that the BLA submitted to the FDA was not complete and, therefore, CytoDyn's April 27, 2020, press release announcing a "completed" BLA was false. **POURHASSAN** engaged in at least the May 1, 2020, and May 4, 2020, transactions while in possession of additional material information not known to the public, namely that the FDA had already communicated to CytoDyn through **KAZEMPOUR** and Amarex, as CytoDyn's regulatory agent, that (i) the BLA was not complete and would not be reviewed, and (ii) the April 27, 2020, press release that **POURHASSAN** caused to be issued contained "misinformation" that must be corrected. After paying for the CytoDyn stock shares at the option purchase price and paying taxes on the subsequent stock sales, **POURHASSAN** personally gained approximately $4.4 million.

POURHASSAN Falsely Claimed that a Complete BLA Would and Had Been Submitted Knowing that CytoDyn Did Not Possess the Necessary Data to Complete the BLA

44. On or about May 4, 2020, **POURHASSAN** filmed a video interview, which **POURHASSAN** caused to be disseminated via the Internet, in which he made materially false and misleading representations to conceal the fraudulent scheme on investors and the fact that he traded CytoDyn stock based on material, non-public information. **POURHASSAN** explained that he "exercised [his] options" in order to provide the company with funding for the following five to six weeks, which "took a tremendous beating on [him]" because he "ha[d] to pay hefty taxes[.]" **POURHASSAN** added, "I try to sacrifice for the company anytime I can." In truth and in fact, **POURHASSAN** had exercised his options based on material non-public information and personally gained approximately $4.4 million from this insider trading.

45. On or about May 4, 2020, and again on or about May 6, 2020, **POURHASSAN** caused CytoDyn to issue press releases that represented that "the [BLA] will be considered completed after the clinical datasets are submitted on May 11, 2020." In each press release, those representations were placed at the end of a boilerplate paragraph generally describing leronlimab and HIV that was included in nearly all of CytoDyn's press releases. Each of those press releases not only omitted important information about what the FDA had communicated and why the BLA would not be considered completed until after the clinical datasets were submitted, but also failed to disclose that CytoDyn had submitted an incomplete BLA (and thus failed to correct the inaccurate April 27, 2020, press release) and did not have the information necessary to complete the BLA submission.

46. It was not until on or about May 8, 2020, after **POURHASSAN** had gained approximately $4.4 million through insider trading, that CytoDyn issued a press release titled "CytoDyn Clarifies Status of [BLA]" that stated in the opening paragraph that the company "today

further clarified the status of [its] submission of its [BLA] . . . . The BLA will not be considered completed until the Company submits to the FDA clinical datasets required to address FDA comments it received in March 2020, as described in the Company's press releases on May 4 and May 6, 2020. CytoDyn expects to submit these clinical datasets on May 11, 2020." Even **POURHASSAN**'s and CytoDyn's representations in this May 8, 2020 press release were materially false and misleading because the release failed to disclose that CytoDyn had submitted an incomplete BLA (and thus failed to correct the inaccurate April 27, 2020, press release) and did not have the information necessary to complete the BLA submission.

47. On or about May 13, 2020, **POURHASSAN** and CytoDyn issued a press release claiming that CytoDyn "Completed Submission of All Remaining Parts of [BLA] on May 11, 2020." **POURHASSAN**'s and CytoDyn's representations in this press release were materially false and misleading because, at a minimum, **POURHASSAN** and CytoDyn knew that the BLA did not contain data required to support the 700mg dosage—because no analysis had been performed to produce such data and CytoDyn did not possess it.

48. On or about June 8, 2020, **POURHASSAN** and CytoDyn issued a press release touting a "BLA Acknowledgement Letter From the FDA" and suggesting that the FDA could inform CytoDyn by July 10, 2020, of its target date for completing review of the BLA. **POURHASSAN**'s and CytoDyn's representations in this press release were materially false and misleading because, in truth and in fact, and as **POURHASSAN** and CytoDyn knew, the critical dose justification data that was necessary for FDA to conduct its review had not been submitted with the BLA.

49. On or about June 9, 2020, and June 10, 2020, **KAZEMPOUR** exercised stock options and sold his approximately 150,000 shares of CytoDyn stock valued at $427,500.

50. On or about August 14, 2020, CytoDyn submitted its annual SEC report on SEC Form 10-K, which was available via the Internet to the investing public throughout the United States, including in the District of Maryland. **POURHASSAN** reviewed, approved, and signed this filing. **KAZEMPOUR** was responsible for reviewing and approving the regulatory-related contents of the filing in his role on CytoDyn's Disclosure Committee. **POURHASSAN**, CytoDyn, **KAZEMPOUR**, and Amarex used CytoDyn's 10-K filing to conceal their prior conduct in furtherance of the conspiracy and schemes, and to continue to mislead investors about the prospects for and timing of resubmitting a completed BLA to the FDA. For example, CytoDyn's 10-K filing included the following representations:

> As of the date of this filing, the Company had filed all three portions of its BLA, however, in July 2020, the Company received a Refusal to File letter from the FDA requesting additional information. The Company has requested a Type A meeting and plans to supply the additional information in a timely manner.
>
> * * *
>
> The BLA was initially submitted with the FDA in April 2020 and the BLA submission was completed on May 11, 2020. In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA filing requesting additional information, and the Company has requested a Type A meeting to discuss the FDA's request for additional information, which the Company expects will be resolved on a timely basis during calendar year 2020.
>
> * * *
>
> In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA submission in April and May of 2020 for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients. The FDA informed the Company its BLA did not contain certain information needed to complete a substantive review and therefore, the FDA would not file the BLA. The FDA's request does not require any additional clinical trials to be conducted, rather that the Company conduct specifically requested additional analysis of the completed trials data. The Company has scheduled a Type A meeting to discuss the FDA's request for

additional information. The Company expects to resubmit the BLA with the additionally required data by the end of calendar year 2020.

POURHASSAN's, CytoDyn's, **KAZEMPOUR**'s, and Amarex's representations in the 10-K filing were materially false and misleading because they:

a. continued to suggest that CytoDyn submitted the BLA in April 2020 without disclosing that, at that time, **POURHASSAN**, CytoDyn, **KAZEMPOUR**, and Amarex knew that the submission was incomplete and that the FDA would issue a refuse to file notice in response, and they nonetheless submitted it;

b. concealed the true nature of the FDA's numerous concerns with the BLA submission (which included dozens of deficiencies) and instead misleadingly suggested that the FDA merely wanted more information about leronlimab; to the contrary, on or about July 8, 2020, the FDA had issued a Refusal to File letter to CytoDyn through **KAZEMPOUR** as CytoDyn's regulatory agent. The FDA stated that the BLA "has numerous omissions and inadequacies so severe as to render the application incomplete and also introduces significant impediments to a prompt and meaningful review because there is the need for substantial amounts of additional data and analyses along with corrections in datasets." Most notably, the letter identified the lack of dose justification data as an impediment to review despite multiple prior occasions on which the FDA informed CytoDyn and Amarex that such data were required in the BLA submission; and

c. provided a false and misleading timeline for resubmission that **POURHASSAN** selected to inflate and maintain CytoDyn's stock price and raise new money from investors, and not based on whether CytoDyn could meet the FDA requirements for resubmission.

POURHASSAN Used Investor Money to Silence His Critics and Conceal the Fraud

51. To respond to public criticism about his conduct, and in furtherance of the scheme to defraud and raise new money from investors, **POURHASSAN** hired and paid with CytoDyn funds an investor-facing media firm to film video interviews, which were posted on the Internet. **POURHASSAN** scripted the questions asked to him in the video interviews, which frequently allowed him to attack individuals who published critical comments in online news articles and chat boards, or elsewhere on the Internet, in furtherance of and in order to conceal the fraudulent scheme.

52. In addition, **POURHASSAN** hired and paid with CytoDyn funds a stock promoter to respond to critical commentary (without attribution to **POURHASSAN** or CytoDyn) in online chat boards and elsewhere on the Internet, in furtherance of and in order to conceal the fraudulent scheme on investors.

KAZEMPOUR Made Materially False Statements to Federal Agents Regarding His Ownership of CytoDyn Stock

53. On or about July 7, 2021, federal law enforcement agents conducted a voluntary interview of **KAZEMPOUR** at Amarex's offices in Germantown, Maryland, relating to Amarex's work for **POURHASSAN** and CytoDyn. During the interview, **KAZEMPOUR** falsely stated that he had only ever owned a "couple hundred" shares of CytoDyn stock, a "hundred or two hundred" shares, or a "bonus of two hundred share[s]" that CytoDyn had awarded him, which **KAZEMPOUR** also referred to as "options." In truth and in fact, **KAZEMPOUR** had not received a "hundred or two hundred" shares of CytoDyn stock, but as further alleged above in Paragraph 41, and as **KAZEMPOUR** knew, he had been given warrants to purchase 150,000 shares of CytoDyn stock, which **KAZEMPOUR** also referred to as "options" in contemporaneous communications, that he attempted to exercise the day after CytoDyn falsely announced that it

submitted a completed BLA to the FDA, and that **KAZEMPOUR** ultimately did exercise to purchase and sell CytoDyn stock in or around June 2020.

In violation of Title 18, United States Code, Section 371.

COUNT 2-4
(15 U.S.C. §§ 78j(b); 78ff; 17 C.F.R. § 240.10b-5 – Securities Fraud)

1. Paragraphs 1 through 10 and 12 through 53 of Count One are hereby realleged and incorporated by reference herein as though fully set forth in this Count of the Indictment.

2. From at least in or around 2018 through at least in or around 2021, within the District of Maryland and elsewhere, the defendants,

NADER POURHASSAN
and
KAZEM KAZEMPOUR,

did knowingly and willfully, directly and indirectly, by use of the means and instrumentalities of interstate commerce, and of the mails, in connection with the purchase and sale of securities, use and employ, and cause others to use and employ, manipulative and deceptive devices and contrivances, in violation of Title 17, Code of Federal Regulations, Section 240.10b-5 by: (a) employing, and causing others to employ, devices, schemes, and artifices to defraud; (b) making, and causing others to make, untrue statements of material fact and omitting to state, and causing others to omit to state, material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; and (c) engaging, and causing others to engage, in acts, practices, and courses of business which operated and would operate as a fraud and deceit upon persons, to wit: to defraud investors in CytoDyn through materially false and misleading representations relating to CytoDyn's investigation and attempted development of leronlimab as a potential treatment for HIV, including the timeline and status of CytoDyn's regulatory submissions to, and review of leronlimab by, the FDA.

On or about the dates set forth below, each such date constituting a separate count of this Indictment, in the District of Maryland and elsewhere, the defendants **NADER POURHASSAN** and **KAZEM KAZEMPOUR**, knowingly used, and caused to be used, any means and instruments

of transportation and communication in interstate commerce and the use of the mails in furtherance of the fraudulent conduct:

COUNT	DATE	INTERSTATE COMMUNICATION
2	April 14, 2020	**POURHASSAN** sent the email to **KAZEMPOUR** and Amarex Executive 1, as described in Paragraph 37 above.
3	April 27, 2020	**KAZEMPOUR** and Amarex filed an incomplete BLA on CytoDyn's behalf with the FDA, as described in Paragraph 38 above.
4	August 14, 2020	**POURHASSAN** and **KAZEMPOUR** caused CytoDyn to submit its annual SEC filing on SEC Form 10-K, as described in Paragraph 50 above.

In violation of Title 15, United States Code, Sections 78j and 78ff, Title 17, Code of Federal Regulations, Section 240.10b-5, and Title 18, United States Code, Section 2.

COUNTS 5-8
(18 U.S.C. § 1343 - Wire Fraud)

1. Paragraphs 1 through 10 and 12 through 53 of Count One are hereby realleged and incorporated by reference herein as though fully set forth in this Count of the Indictment.

2. From at least in or around 2018 through at least in or around 2021, within the District of Maryland and elsewhere, the defendants,

NADER POURHASSAN
and
KAZEM KAZEMPOUR,

did knowingly and with the intent to defraud, having devised and intending to devise a scheme and artifice to defraud, and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing such pretenses, representations, and promises were false and fraudulent when made, transmit and cause to be transmitted, by means of wire communications in interstate and foreign commerce, writings, signals, pictures, and sounds, for the purpose of executing such scheme and artifice, to wit: to defraud investors in CytoDyn through materially false and misleading representations relating to CytoDyn's investigation and attempted development of leronlimab as a potential treatment for HIV, including the timeline and status of CytoDyn's regulatory submissions to, and review of leronlimab by, the FDA.

3. On or about the dates set forth below, each such date constituting a separate count of this Indictment, in the District of Maryland and elsewhere, the defendants **NADER POURHASSAN** and **KAZEM KAZEMPOUR,** for the purpose of executing and attempting to execute the scheme and artifice to defraud, did knowingly transmit and cause to be transmitted in interstate commerce by means of a wire communication, certain signals, signs and sounds, as set forth below:

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

In violation of Title 18, United States Code, Section 1343.

COUNT 9
(15 U.S.C. §§ 78j(b); 78ff; 17 C.F.R. § 240.10b-5 – Securities Fraud)

1. Paragraphs 1 through 10 and 12 through 53 of Count One are hereby realleged and incorporated by reference herein as though fully set forth in this Count of the Indictment.

PURPOSE OF THE SCHEME AND ARTIFICE

2. It was the purpose of the scheme and artifice for the defendant, **NADER POURHASSAN**, to unjustly enrich himself by: (i) making, and causing to be made, materially false and misleading representations to investors relating to CytoDyn's investigation and attempted development of leronlimab as a potential treatment for COVID-19, including its purported efficacy; (ii) concealing from investors the true facts; (iii) diverting the proceeds of the scheme and artifice for his personal use and benefit; and (iv) concealing the scheme from regulators, law enforcement, investors, and the media.

MANNER AND MEANS OF THE SCHEME AND ARTIFICE

3. Paragraphs 13, and 19 through 20 of the Manner and Means of the Conspiracy and Schemes to Defraud section of Count 1 of this Indictment are hereby re-alleged and fully incorporated herein by reference.

4. The manner and means by which **POURHASSAN** sought to accomplish the purpose of the scheme and artifice further included, but were not limited to, the following:

5. On or about December 22, 2020, **POURHASSAN** and CytoDyn issued a press release claiming, among other things, that CytoDyn's CD10 clinical trial for COVID-19 "produced statistically significant results for NEWS2." This was materially false and misleading because, in truth and in fact, as **POURHASSAN** and CytoDyn knew, the data had not been run through the proper statistical tests to correct for multiplicity and therefore were not statistically significant. On

or about December 23, 2020, the FDA held a conference call to inform CytoDyn that its claims in the December 22, 2020, press release were misleading.

6. On or about December 24, 2020, **POURHASSAN** and CytoDyn issued a press release that omitted the material information that the FDA had informed CytoDyn that its December 22, 2020, press release was misleading and the CD10 clinical trial data were not statistically significant. Instead, at the end of a lengthy quote attributed to **POURHASSAN**, the press release stated only that the "CD10 trial will not support an eIND request."

7. By in or around February 2021, CytoDyn received the results of its CD12 clinical trial for COVID-19 that showed that leronlimab failed to meet the primary or secondary endpoints (i.e., goals) of the study. CytoDyn and Amarex prepared an executive summary report (the "Executive Summary") for the FDA discussing the CD12 clinical trial results. **POURHASSAN** urged CytoDyn employees, including CytoDyn Executive 1, to make the Executive Summary more positive than the data supported.

8. In or around February 2021, **POURHASSAN** became concerned with CytoDyn's declining stock price and asked Amarex to prepare an addendum to the Executive Summary (the "Addendum"). Amarex drafted the Addendum at **POURHASSAN**'s direction, with input from other CytoDyn executives. The Addendum included post hoc analysis of data for patient subpopulations in an effort to suggest that leronlimab was effective in treating certain COVID-19 patient subgroups. CytoDyn Executive 1 warned **POURHASSAN** that the analysis was not statistically or scientifically sound. **KAZEMPOUR** also expressed concern about the statistical analysis that **POURHASSAN** wanted to present in the Addendum. Despite knowing that **POURHASSAN**'s request was improper, **KAZEMPOUR** told CytoDyn Executive 1 that Amarex would include the post hoc analysis of data because Amarex does what its client asked.

9. At **POURHASSAN**'s direction, CytoDyn and Amarex submitted the Addendum to the FDA. Specifically, on or about February 23, 2021, **POURHASSAN** sent **KAZEMPOUR** and others an email with the subject line, "CytoDyn – Leronlimab_CD12_COVID-19_Executive Summary_Addendum FINAL," instructing **KAZEMPOUR** to submit the addendum to the FDA. The FDA subsequently disagreed with the analysis in the Addendum and called an urgent meeting with CytoDyn and Amarex to express its concerns that the post hoc analysis of COVID-19 patient subgroup data was misleading.

10. **POURHASSAN** and CytoDyn repeatedly made materially false and misleading representations of leronlimab's effectiveness as a COVID-19 treatment based on patient subpopulations that they knew, because the FDA and CytoDyn personnel had explicitly informed them, derived from flawed calculations and results that were neither statistically significant nor scientifically sound. For example:

a. On or about March 5, 2021, **POURHASSAN** and CytoDyn issued a press release claiming that "CytoDyn's Phase 3 Trial Demonstrates Safety, a 24% Reduction in Mortality [for] Critically Ill COVID-19 Patients Treated with Leronlimab."

b. On or about March 8, 2021, **POURHASSAN** caused CytoDyn to file a Current Report on SEC Form 8-K that attached a combined version of the Executive Summary report to FDA and analysis from the Addendum, despite the prior warnings from CytoDyn and Amarex personnel, and the FDA, that the analysis in the Addendum was misleading.

c. On or about March 30, 2021, **POURHASSAN** and CytoDyn issued a press release stating "CytoDyn's Leronlimab Decreased Mortality at 14 Days by 82% With

Statistically Significant P-Value of 0.0233 Amongst Critically Ill COVID-19 Patients."

11. In response to **POURHASSAN**'s and CytoDyn's serial misrepresentations regarding leronlimab's effectiveness as a COVID-19 treatment, on or about May 17, 2021, the FDA released a public statement on its website to correct CytoDyn's public misrepresentations regarding leronlimab. The FDA's "Statement on Leronlimab" explained, in pertinent part:

> Focusing on only the most favorable of many subgroup analyses, even if the sub-groups are pre-specified, can lead to overestimating the evidence of benefit, because regardless of a drug's true efficacy, some analyses are likely to appear favorable by chance when a large number of analyses are conducted.
>
> With the conclusion of both the CD10 and CD12 clinical trials, it has become clear that the data currently available do not support the clinical benefit of leronlimab for the treatment of COVID-19. . . .
>
> CytoDyn has publicly communicated differences in small subgroups from the CD12 trial (e.g., a sub-group analysis of 62 of the 394 patients studied) suggesting that the data demonstrated a mortality benefit in certain patients who had received leronlimab. Subgroup analyses have well-established limitations, especially in the context of a clinical trial that has failed to show a benefit in the overall study population. For example, subgroups are often small, and therefore imbalances are common. Here, the data from CD12 illustrated imbalances in mortality among subgroups, some favoring leronlimab and some favoring placebo. None of these analyses met statistical significance when using established and reliable analytical methods that correct for multiple comparisons.

On or about September 22, 2021, notwithstanding the FDA's repeated warnings and public statement regarding leronlimab and COVID-19, **POURHASSAN** filmed a video interview that was posted and publicly available on the Internet in which he again made materially false and misleading representations regarding leronlimab's effectiveness as a treatment for critically ill COVID-19 patients.

THE CHARGE

12. From at least in or around 2020, through at least in or around 2021, within the District of Maryland and elsewhere, the defendant,

NADER POURHASSAN,

did knowingly and willfully, directly and indirectly, by use of the means and instrumentalities of interstate commerce, and of the mails, in connection with the purchase and sale of securities, use and employ, and cause others to use and employ, manipulative and deceptive devices and contrivances, in violation of Title 17, Code of Federal Regulations, Section 240.10b-5 by: (a) employing, and causing others to employ, devices, schemes, and artifices to defraud; (b) making, and causing others to make, untrue statements of material fact and omitting to state, and causing others to omit to state, material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; and (c) engaging, and causing others to engage, in acts, practices, and courses of business which operated and would operate as a fraud and deceit upon persons, to wit: to defraud investors in CytoDyn through materially false and misleading representations and material omissions relating to CytoDyn's investigation and attempted development of leronlimab as a potential treatment for COVID-19, including the results and significance of clinical trials and the status of CytoDyn's regulatory submissions to, and review of leronlimab by, the FDA.

On or about March 8, 2021, the defendant **NADER POURHASSAN,** knowingly used, and caused to be used, any means and instruments and transportation or communication in interstate commerce and the use of the mails in furtherance of the fraudulent conduct to wit: **POURHASSAN** caused CytoDyn to file a Current Report on SEC Form 8-K that attached a combined version of the Executive Summary report to FDA and analysis from the Addendum,

despite the prior warnings from CytoDyn and Amarex personnel, and the FDA, that the analysis in the Addendum was misleading.

In violation of Title 15, United States Code, Sections 78j and 78ff, Title 17, Code of Federal Regulations, Section 240.10b-5, and Title 18, United States Code, Section 2.

COUNT 10
(18 U.S.C. § 1343 - Wire Fraud)

1. Paragraphs 1 through 10 and 12 through 53 of Count One and paragraphs 2 through 11 of Count Nine are hereby realleged and incorporated by reference herein as though fully set forth in this Count of the Indictment.

2. From at least in or around 2020, through at least in or around 2021, within the District of Maryland and elsewhere, the defendant,

NADER POURHASSAN,

did knowingly and with the intent to defraud, having devised and intending to devise a scheme and artifice to defraud, and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing such pretenses, representations, and promises were false and fraudulent when made, transmit and cause to be transmitted, by means of wire communications in interstate and foreign commerce, writings, signals, pictures, and sounds, for the purpose of executing such scheme and artifice, to wit: to defraud investors in CytoDyn through materially false and misleading representations and material omissions relating to CytoDyn's investigation and attempted development of leronlimab as a potential treatment for COVID-19, including the results and significance of clinical trials and the status of CytoDyn's regulatory submissions to, and review of leronlimab by, the FDA.

3. On or about February 23, 2021, in the District of Maryland and elsewhere, the defendant, **NADER POURHASSAN**, for the purpose of executing and attempting to execute the scheme and artifice to defraud, did knowingly transmit and cause to be transmitted in interstate commerce by means of a wire communication, certain signals, signs and sounds, to wit: an e-mail communication from **POURHASSAN** to **KAZEMPOUR** and others, with the subject line "CytoDyn – Leronlimab_CD12_COVID-19_Executive Summary_Addendum FINAL,"

instructing **KAZEMPOUR** to submit the Addendum to the FDA.

In violation of Title 18, United States Code, Section 1343.

COUNT 11-13
(15 U.S.C. §§ 78j(b); 78ff; 17 C.F.R. § 240.10b-5 – Insider Trading)

1. Paragraphs 1 through 10 and 12 through 53 of Count One are hereby realleged and incorporated by reference herein as though fully set forth in this Count of the Indictment.

2. From at least in or around April 2020, through at least in or around May 2020, within the District of Maryland and elsewhere, the defendant,

NADER POURHASSAN,

did knowingly and willfully, directly and indirectly, by use of the means and instrumentalities of interstate commerce, and of the mails, in connection with the purchase and sale of securities, use and employ, and cause others to use and employ, manipulative and deceptive devices and contrivances, in violation of Title 17, Code of Federal Regulations, Section 240.10b-5 by: (a) employing, and causing others to employ, devices, schemes, and artifices to defraud; (b) making, and causing others to make, untrue statements of material fact and omitting to state, and causing others to omit to state, material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; and (c) engaging, and causing others to engage, in acts, practices, and courses of business which operated and would operate as a fraud and deceit upon persons, to wit: on the basis of material, non-public information obtained from his employer, CytoDyn, **NADER POURHASSAN**, executed and caused to be executed trades in the securities of CytoDyn, as follows:

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

In violation of Title 15, United States Code, Sections 78j and 78ff, Title 17, Code of Federal Regulations, Section 240.10b-5.

COUNT 14
(18 U.S.C. § 1001 – False Statement)

1. Paragraphs 1 through 10 and 12 through 53 of Count One are hereby realleged and incorporated by reference herein as though fully set forth in this Count of the Indictment.

2. On or about July 7, 2021, in the District of Maryland and elsewhere, in a matter within the jurisdiction of the executive branch of the Government of the United States, the defendant,

KAZEM KAZEMPOUR,

did knowingly and willfully make materially false, fictitious, and fraudulent statements and representations, to wit, when being interviewed by law enforcement agents, **KAZEMPOUR** falsely stated that he only ever owned a "couple hundred" shares of CytoDyn stock, a "hundred or two hundred" shares, or a "bonus of two hundred share[s]" that CytoDyn had awarded him, which **KAZEMPOUR** also referred to as "options." In truth and in fact, **KAZEMPOUR** had not received a "hundred or two hundred" shares of CytoDyn stock, but as further alleged above in Paragraph 41, and as **KAZEMPOUR** knew, he had been given warrants to purchase 150,000 shares of CytoDyn stock, which **KAZEMPOUR** also referred to as "options" in contemporaneous communications, that he attempted to exercise the day after CytoDyn falsely announced that it submitted a completed BLA to the FDA, and that **KAZEMPOUR** ultimately did exercise to purchase and sell CytoDyn stock in or around June 2020.

In violation of Title 18, United States Code, Section 1001(a)(2).

FORFEITURE ALLEGATION

The Grand Jury for the District of Maryland further finds that:

1. Pursuant to Federal Rule of Criminal Procedure 32.2, notice is hereby given to the defendants that the United States will seek forfeiture as part of any sentence in accordance with 18 U.S.C. § 981(a)(1)(C), 21 U.S.C. § 853(p), and 28 U.S.C. § 2461(c) in the event of a defendant's conviction on any of the offenses charged in Counts One through Eight of this Indictment.

2. Upon conviction of any of the offenses set forth in Counts One through Thirteen of this Indictment, the defendants,

NADER POURHASSAN
and
KAZEM KAZEMPOUR

shall forfeit to the United States, pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to the offense(s) of conviction, including a money judgment in the amount of proceeds he obtained.

Substitute Assets

3. If any of the property subject to forfeiture, as a result of any act or omission of the defendants:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty

the United States shall be entitled to forfeiture of substitute property pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c).

All pursuant to Title 18, United States Code, Section 981(a)(1)(C), Title 21, United States Code, Section 853, and Title 28, United States Code, Section 2461(c).

DATED: December 15, 2022, at Baltimore, Maryland.

EREK L. BARRON
United States Attorney for the District of Maryland

GLENN S. LEON
Chief
Fraud Section, Criminal Division
United States Department of Justice

A TRUE BILL:

12/15/2022
Date

SIGNATURE REDACTED

Foreperson