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UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

-against-

NADER POURHASSAN and KAZEM KAZEMPOUR, (Montgomery County)

Defendants.

COMPLAINT

22 Civ. 3284

JURY TRIAL DEMANDED

Plaintiff Securities and Exchange Commission ("Commission"), for its Complaint against Defendants Nader Pourhassan ("Pourhassan") and Kazem Kazempour ("Kazempour") (collectively, "Defendants"), alleges as follows:

SUMMARY

1. This civil enforcement action concerns fraud and insider trading by Defendant Pourhassan, the former CEO of CytoDyn Inc. ("CytoDyn"), a publicly-traded, clinical-stage biotechnology company.

2. Beginning in 2018 and through 2021, Pourhassan repeatedly made, or caused CytoDyn to make, materially false and misleading statements to the public about the progress of

the company's clinical research treatments for human immunodeficiency virus ("HIV") and COVID-19.

3. In April 2020, Pourhassan caused CytoDyn to falsely announce that it had submitted a "completed" Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA"), which would have been a key milestone for the company. In reality, as Pourhassan knew, CytoDyn's BLA submission was woefully incomplete—it was missing key clinical data that the FDA had been telling the company it must include in its BLA submission for nearly two years.

4. Within two days, the FDA alerted CytoDyn to the falsity of this press release, which Pourhassan edited, reviewed, and approved. But, instead of alerting the public, Pourhassan executed on his own plan (in violation of corporate policies) to exercise stock options and liquidate stock while the company's stock price was artificially inflated. All told, in the days following the false press release, Pourhassan sold approximately $15.8 million worth of CytoDyn stock, netting profits of more than $4.7 million.

5. Defendant Kazempour, the CEO of a contract research organization CytoDyn hired to interface with the FDA and assist with its BLA submission, participated in the scheme by signing off on the incomplete BLA at Pourhassan's direction to help Pourhassan boost the stock price. Though Kazempour knew the FDA would ultimately reject the submission (which it did), he managed to exercise his own CytoDyn stock options and sell more than $420,000 worth of CytoDyn stock, for profits of more than $340,000, before the public knew what he knew.

VIOLATIONS

6. By virtue of the foregoing conduct and as alleged further herein, Pourhassan has violated Section 17(a) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. § 77q(a)] and

Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. § 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. § 240.10b-5].

7. By virtue of the foregoing conduct and as alleged further herein, Kazempour has violated Securities Act Section 17(a) [15 U.S.C. § 77q(a)] and Exchange Act Section 10(b) [15 U.S.C. § 78j(b)] and Rules 10b-5(a) and 10b-5(c) thereunder [17 C.F.R. §§ 240.10b-5(a) and 240.10b-5(c)].

8. Unless Defendants are restrained and enjoined, they will engage in the acts, practices, transactions, and courses of business set forth in this Complaint or in acts, practices, transactions, and courses of business of similar type and object.

NATURE OF THE PROCEEDINGS AND RELIEF SOUGHT

9. The Commission brings this action pursuant to the authority conferred upon it by Securities Act Sections 20(b) and 20(d) [15 U.S.C. §§ 77t(b) and 77t(d)], Exchange Act Section 21(d) [15 U.S.C. § 78u(d)], and Exchange Act 21A(a) [15 U.S.C. § 78u-1(a)].

10. The Commission seeks a final judgment: (a) permanently enjoining Defendants from violating the federal securities laws and rules this Complaint alleges they have violated; (b) ordering Defendants to disgorge the ill-gotten gains they received as a result of the violations alleged here and to pay prejudgment interest thereon pursuant to Exchange Act Sections 21(d)(5) and 21(d)(7) [15 U.S.C. §§ 78u(d)(5), and 78u(d)(7)]; (c) ordering Defendants to pay civil money penalties pursuant to Securities Act Section 20(d) [15 U.S.C. § 77t(d)] and Exchange Act Section 21(d)(3) [15 U.S.C. § 78u(d)(3)]; (d) ordering Pourhassan to pay a civil money penalty pursuant to Exchange Act 21A(a) [15 U.S.C. § 78u-1(a)]; (e) permanently prohibiting Defendants from serving as an officer or director of any company that has a class of securities registered under Exchange Act Section 12 [15 U.S.C. § 78l] or that is required to file reports

under Exchange Act Section 15(d) [15 U.S.C. § 78o(d)], pursuant to Securities Act Section 20(e) [15 U.S.C. § 77t(e)] and Exchange Act Section 21(d)(2) [15 U.S.C. § 78u(d)(2)]; and (f) ordering any other and further relief the Court may deem just and proper.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to Securities Act Section 22(a) [15 U.S.C. § 77v(a)] and Exchange Act Section 27 [15 U.S.C. § 78aa].

12. Defendants, directly and indirectly, have made use of the means or instrumentalities of interstate commerce or of the mails in connection with the transactions, acts, practices, and courses of business alleged herein.

13. Venue lies in this District under Securities Act Section 22(a) [15 U.S.C. § 77v(a)] and Exchange Act Section 27 [15 U.S.C. § 78aa]. Kazempour resides in Rockville, Maryland, and transacted business at his offices in Germantown, Maryland. Additionally, certain acts, practices, transactions, and courses of business alleged in this Complaint occurred within this District, including Pourhassan's and Kazempour's meetings with and BLA submission to the FDA (whose offices are located in Silver Spring, Maryland) as well as purchases of CytoDyn stock around the times of the materially false and misleading statements described herein by at least 400 investors located in this District.

DEFENDANTS

14. **Pourhassan**, age 59, resides in Lake Oswego, Oregon. He was the CEO, president, and a director of CytoDyn from 2012 until January 24, 2022, when the company terminated his employment and removed him from the board of directors.

15. **Kazempour**, age 69, resides in Rockville, Maryland. He is the co-founder of Amarex Clinical Research, LLC ("Amarex"), a contract research organization for which he has

served as president and CEO since 1998. Previously, from approximately 1991 through 1995, Kazempour worked in the FDA's Division of Antiviral Drug Products.

FACTS

I. BACKGROUND ON CYTODYN

16. CytoDyn was originally a Colorado corporation formed in May 2002 under the name RexRay Corporation. The company was reincorporated in Delaware in August 2015, and it remains a Delaware corporation today.

17. At all relevant times, CytoDyn's common stock has been registered with the Commission pursuant to Exchange Act Section 12(g) [15 U.S.C. § 78l(g)].

18. At all relevant times, prices of CytoDyn common stock have been quoted by OTCQB, an interdealer quotation service operated by OTC Markets Group, Inc., using the ticker symbol CYDY.

19. CytoDyn is a clinical-stage biotechnology company with its principal business office in Vancouver, Washington.

20. At all relevant times, CytoDyn did not generate revenue; rather, it has focused on the clinical development of treatments for various diseases, including HIV and COVID-19.

21. Specifically, CytoDyn sought to develop treatments using a monoclonal antibody called leronlimab (also called PRO 140), which was the company's sole potential product candidate.

22. A BLA is a request to the FDA for permission to introduce, or deliver to introduce, a biologic product into interstate commerce—that is, to market and sell a biologic product to treat a disease or condition.

23. To be considered complete, a BLA submission must include data sufficient in quality and quantity to establish the safety, potency, and purity of a product, which includes data from both pre-clinical and clinical studies.

24. Generally, once an applicant makes a BLA submission, the FDA conducts a preliminary review within 60 days of receipt of the submission and informs the applicant by the 74th day after receipt whether an application is sufficiently complete to permit substantive review.

25. If the FDA determines that a BLA is not sufficiently complete during this preliminary review period, it will issue the applicant a "Refuse to File" letter.

26. The filing of a completed BLA is an important milestone for an early-stage biotechnology company like CytoDyn because it indicates that the company is progressing in its efforts to obtain FDA approval to market and sell a new drug.

27. Amarex, which has offices in Germantown, Maryland, provides clinical research management services for "sponsors" (i.e., companies like CytoDyn) who are seeking to file a BLA with the FDA.

28. CytoDyn retained Amarex in or about May 2014 to assist with its clinical trials of leronlimab.

29. Until Amarex and CytoDyn ceased working together in September 2021, CytoDyn was Amarex's largest, most important client.

30. As part of its engagement by CytoDyn, Amarex interfaced directly with, and served as the primary contact for, the FDA for purposes of CytoDyn's expected BLA submission.

31. Kazempour routinely participated in discussions with both the FDA and CytoDyn regarding the progress of the draft BLA materials, including one-on-one discussions with Pourhassan.

32. By at least the end of 2017, Kazempour was also a member of CytoDyn's disclosure committee, a committee which discussed whether there were any material disclosures to report in the company's periodic filings with the Commission.

33. As part of his role as CEO, Pourhassan was integral to the issuance of CytoDyn press releases—he typically reviewed and edited the releases and then approved the final press release before it was issued by the company.

II. CYTODYN BEGINS THE BLA PROCESS AND ISSUES A MATERIALLY FALSE AND MISLEADING PRESS RELEASE IN NOVEMBER 2018.

34. CytoDyn, with the assistance of Kazempour and Amarex, began the process of preparing a BLA submission for the potential use of leronlimab to treat HIV by at least 2018.

35. On April 16, 2018, CytoDyn submitted a request to the FDA for a pre-BLA meeting to discuss the adequacy of their nonclinical, chemistry, manufacturing and controls ("CMC"), and clinical data to support a planned BLA submission.

36. The FDA held the requested pre-BLA meeting with CytoDyn and Amarex on June 18, 2018, at the FDA's offices in Silver Spring, Maryland.

37. Pourhassan and others from CytoDyn attended this meeting, along with Kazempour and others from Amarex.

38. During the meeting, the FDA reviewed the entire BLA process, including the contents and format of a "completed" BLA, which included clinical datasets.

39. The FDA further advised CytoDyn and Amarex at the meeting that this "data should be robust and FDA should not be put in a position to try to summarize or make assumptions about this data."

40. In the months after the pre-BLA meeting, Pourhassan repeatedly set unrealistic internal deadlines concerning CytoDyn's BLA submission. Pourhassan then caused the company to make materially false and misleading public statements that suggested these deadlines were realistic (when they were not).

41. For example, before the market opened on November 13, 2018, CytoDyn issued a materially false and misleading press release concerning its BLA submission timeline.

42. In that press release, CytoDyn stated that it "remains on track to complete its filing of a [BLA] for PRO 140 as a combination therapy for HIV patients with the FDA by the first quarter of 2019."

43. In reality, as Pourhassan knew at the time, this timeline was impossible to meet based on the progress of the company's clinical trials.

44. Pourhassan reviewed and approved this press release before it was issued.

45. After CytoDyn issued this release on November 13, 2018, its stock opened up 5% at $0.59 and the trading volume that day was approximately 279,400 shares—more than double the volume the prior day and nearly double the volume the following day.

46. The November 13, 2018, press release also stated that CytoDyn's clinical trial had shown HIV viral load suppression at a "92% Responder Rate" when the tested dosage of PRO 140 was increased from 350 milligrams to 700 milligrams.

47. During a teleconference on December 14, 2018, between the FDA, CytoDyn (including Pourhassan), and Amarex (including Kazempour), the FDA stated that it had not seen the study data to validate this information.

48. Additionally, on December 28, 2018, the FDA sent a memorandum to Kazempour in which it raised concerns about an "overly optimistic timeline for your BLA submission" given CytoDyn's request to allow amendments to its ongoing clinical trials to collect at least 12 weeks of data from at least 100 subjects receiving the higher 700 milligram dosage.

49. The memorandum reminded CytoDyn of the information it needed to submit with its BLA submission, which included clinical datasets.

50. The memorandum also raised questions about how the "92% Responder Rate" was calculated and asked for more data before the FDA could agree to permit the increased dosage to be used for all subjects.

51. On January 3, 2019, Kazempour responded to the FDA thanking them for the feedback and the summary of the information to be included in their BLA submission.

III. AS CYTODYN FAILS TO FILE ITS BLA IN 2019 AND EARLY 2020, POURHASSAN GROWS CONCERNED ABOUT THE STOCK PRICE IMPACT.

52. 2019 came and went without CytoDyn filing its BLA.

53. Throughout 2019, CytoDyn (through Kazempour and Amarex) and the FDA were in communication regarding information and data that would be necessary in order for CytoDyn to file a completed BLA.

54. For example, on December 16, 2019, the FDA sent a memorandum to Kazempour in which it stated that, "[w]ith your BLA submission, you should submit an integrated assessment and detailed summary that supports your selected dose and incorporates virologic outcomes, safety data (including laboratory abnormalities), exposure related data (including

population pharmacokinetics and exposure response relationship analyses), receptor occupancy data (including both method validation report and bioanalytical report of clinical samples), and anti-idiotypic antibody data (including both method validation report and bioanalytical report of clinical samples)."

55. The memorandum again reminded Kazempour that "the data you submit with your BLA must be sufficiently complete and accurate to allow FDA reviewed to evaluate your selected dose."

56. At this time, Pourhassan sought to tie his own compensation to the BLA filing.

57. On December 19, 2019, Pourhassan sought and obtained approval from CytoDyn's board to award him (and others) stock options that would vest upon the filing of the company's BLA submission.

58. Specifically, Pourhassan received a stock option award of 2,000,000 shares of CytoDyn common stock, with an exercise price of $0.63, which would automatically vest upon the filing of the BLA submission.

59. Pourhassan's unrealistic expectations and deadlines put pressure on both CytoDyn and Amarex employees.

60. For example, CytoDyn Employee-1 was working their team seven days a week to try to meet Pourhassan's deadlines.

61. Amarex Employee-1 viewed CytoDyn as a "pushy" client that routinely set unreasonable turnaround times for various deliverables.

62. In late December 2019, Pourhassan set a January 2020 deadline for CytoDyn to make its BLA submission.

63. But, by January 2020, there were a number of deliverables necessary for the BLA submission still pending.

64. In mid-January 2020, Amarex Employee-2 told Pourhassan that it was not possible to submit the BLA by the end of the month.

65. Nevertheless, in a text message on January 29, 2020, Pourhassan asked Amarex Employee-2 whether CytoDyn could file its BLA submission the next day.

66. Pourhassan was concerned that CytoDyn's BLA filing delays were negatively impacting the company's stock price.

67. For example, in a text message on February 8, 2020, Pourhassan told Kazempour and Amarex Employee-2 that "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."

68. And, in a text message on February 24, 2020, Pourhassan told Kazempour that he was "really in need of your help with our BLA. We signed an extra work order of about $150k so we could get it done by the end of JANUARY and now we are at the end of FEBRUARY and I am losing a lot of credibility among our shareholders."

69. In or about early 2020, Pourhassan asked a CytoDyn consultant for certain data (i.e., receptor occupancy data) required for inclusion in the clinical module for the BLA. The CytoDyn consultant shared with Pourhassan a spreadsheet that indicated that the consultant did not even have the samples needed to generate that data, let alone the data itself.

IV. POURHASSAN CAUSES CYTODYN TO ISSUE A PRESS RELEASE FALSELY STATING THAT IT HAD FILED A "COMPLETED" BLA SUBMISSION.

70. By the beginning of April 2020, after already missing various deadlines set by Pourhassan, Amarex was still seeking to complete the clinical datasets that were needed for the BLA submission.

71. Knowing these clinical datasets were not complete, Pourhassan asked CytoDyn Employee-1 and Amarex Employee-2 in an email on April 6, 2020, "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?"

72. Then, on April 14, 2020, Pourhassan emailed Kazempour along with CytoDyn Employee-1 and Amarex Employee-2, complaining that CytoDyn's stock had dropped "in 1 hour almost 20%" despite the company having released what Pourhassan described as "great results about COVID-19 patients."

73. During this time period in 2020, CytoDyn had also initiated clinical studies to determine if leronlimab could be used to treat COVID-19.

74. Pourhassan further stated in his April 14, 2020, email 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."

75. Accordingly, Pourhassan directed the recipients of his email 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."

76. Pourhassan further stated in his email that, if CytoDyn's stock price continued to drop, the company would have "problems financing itself" and that, as a result "THE MOST IMPORTANT thing now is BLA. Please focus on that urgently only."

77. In response to Pourhassan's instruction, Amarex filed CytoDyn's BLA with the FDA approximately two weeks later on April 27, 2020.

78. Kazempour electronically signed the cover letter for the BLA submission, which was on CytoDyn letterhead, as the "US Agent for CytoDyn, Inc."

79. Kazempour's BLA cover letter made clear that the BLA submission was missing certain datasets and was otherwise not complete. The letter further stated that "[r]evised datasets will be submitted to the BLA as an amendment in May 2020," noting the missing datasets in a table below in red font.

80. Kazempour applied his electronic signature to the BLA cover letter on Sunday, April 26, 2020, the day before the BLA filing itself.

81. The deficiencies in CytoDyn's BLA submission were not trivial; the submission was missing clinical datasets that the FDA had repeatedly reminded Kazempour, Amarex, Pourhassan, and CytoDyn were core to the FDA's substantive review process.

82. As Kazempour himself stated in a declaration he signed in a private litigation between Amarex and CytoDyn, despite repeated warnings, "Pourhassan directed Amarex to file the BLA prematurely, knowing it was incomplete, lacking in appropriate content, and not ready for submission."

83. Citing Pourhassan's April 14, 2020, email, Kazempour further stated in this declaration that Pourhassan's "justification for his premature direction, as stated in his email, stems from a stock price drop and to 'allay investors who are very frustrated with me and CytoDyn.'"

84. Kazempour also stated in his declaration that, at Pourhassan's direction, "Amarex submitted the incomplete and lacking BLA to the FDA," which was "[n]ot surprisingly" rejected as incomplete.

85. Kazempour further admitted in this declaration that "Pourhassan and CytoDyn received exactly what was to be expected, a refusal to file [letter from the FDA] for missing and incomplete information."

86. On April 27, 2020, CytoDyn issued a press release touting its BLA submission before the market opened that day.

87. Specifically, the title of the press release stated that CytoDyn had submitted a "completed" BLA to the FDA for leronlimab as a combination therapy for HIV.

88. The press release further stated that CytoDyn "has submitted the clinical, and the CMC (chemistry, manufacturing and controls) portions of its BLA" to the FDA.

89. Pourhassan himself was quoted in the press release, saying "The submission of the final two parts of the BLA is a significant milestone for the Company, and initiates its transition from a development-stage company to a commercial organization."

90. In reality, as Pourhassan knew, CytoDyn's BLA submission was not complete.

91. As the cover letter signed by Kazempour acknowledged, the BLA did not contain all the information the FDA had previously requested in order to substantively review the submission.

92. Among other deficiencies, the BLA submission lacked required clinical datasets that the FDA had previously advised CytoDyn and Amarex were required for a completed submission.

93. Pourhassan directed CytoDyn employees to prepare the April 27, 2020, press release that touted the submission of a completed BLA, he reviewed drafts and made edits to the release, and he authorized CytoDyn to issue the release.

94. Based on his prior communications with Pourhassan, Kazempour knew or was reckless as to whether Pourhassan would issue a press release stating that CytoDyn had filed a completed BLA when, in fact, it had not.

95. Pourhassan convinced CytoDyn's board of directors to award Kazempour warrants to purchase an additional 200,000 shares of CytoDyn stock as a reward for Kazempour's work in helping to file the (incomplete) BLA submission.

96. On April 24, 2020, Pourhassan texted Kazempour to let him know that CytoDyn's board had approved the issuance of these warrants.

97. Kazempour later texted Pourhassan and asked him to put the warrants in Kazempour's wife's name.

98. On April 27, 2020, after CytoDyn issued this press release, CytoDyn's stock price closed up over 17% on 80% increased trading volume.

V. THE FDA REBUKES CYTODYN FOR ITS FALSE BLA PRESS RELEASE.

99. The FDA's response to CytoDyn's false press release lauding its filing of a completed BLA submission was swift.

100. On April 29, 2020, a senior regulatory project manager at the FDA emailed Kazempour with the subject line "BLA 761144 – Remains Incomplete" and sent the email with "High" importance.

101. In the email, the FDA official stated that CytoDyn's submission included an "incomplete clinical module to support this BLA application" and specifically took issue with the use of the word "completed" in the title of CytoDyn's press release on April 27, 2020.

102. The FDA official also stated in the email that the FDA had informed CytoDyn on multiple occasions, including by providing them with links to guidance, "that the BLA review clock does not begin until a complete BLA was submitted."

103. The FDA official further stated in the email that CytoDyn's "April 27, 2020, submissions do not constitute a completed BLA as CytoDyn has reported to the public via press release," and that "[t]he 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."

104. The FDA official further requested that Kazempour, as CytoDyn's regulatory agent, "take regulatory responsibility for the misinformation released in the aforementioned Press Release by notifying CytoDyn."

105. Amarex Employee-2 forwarded the FDA official's email to Pourhassan the next day, April 30, 2020, at approximately 5:30 p.m. ET.

106. By then, as described in more detail below, Pourhassan had already begun exercising vested stock options and selling CytoDyn shares.

107. On May 4, 2020, CytoDyn issued a press release concerning the possible use of leronlimab for the treatment of COVID-19. The release was titled: "FDA Approves 54 Emergency INDs for Leronlimab Treatment of Coronavirus – CytoDyn Requests Compassionate Use from FDA for COVID."

108. In the middle of the eighth paragraph in that press release, CytoDyn stated that its BLA submission (concerning the possible use of leronlimab for the treatment of HIV) "will be considered completed after the clinical datasets are submitted on May 11, 2020," and conceding that the April 27, 2020, BLA submission had not, in fact, been considered complete by the FDA.

109. Pourhassan reviewed and approved the issuance of this press release by CytoDyn.

110. On May 13, 2020, CytoDyn issued another press release concerning its BLA submission, which stated that the company had completed the submission of all remaining parts on May 11, 2020.

111. Pourhassan reviewed and approved the issuance of this press release by CytoDyn.

112. Again, however, and as Pourhassan well knew, CytoDyn's May 11, 2020, BLA submission was not complete because it did not (and could not have) included the required information, data, and analysis.

113. On July 8, 2020, the FDA sent Kazempour, as the regulatory agent for CytoDyn, a Refuse to File letter for the May 11, 2020, BLA submission.

114. The notice stated that the BLA submission by CytoDyn on May 11, 2020, "does not contain all pertinent information and data needed to complete a substantive review."

115. The notice summarized four sets of deficiencies in the BLA: "Absence of Analyses of Data Supporting the Proposed Dose, "Electronic Dataset Quality Issues," "Absence of Demographic Subset Analyses Needed for Substantive Review of Product Effectiveness and Safety," and "Device-Related Issues."

116. CytoDyn never filed a completed BLA submission with the FDA.

117. On October 28, 2022, CytoDyn announced in a press release that it was withdrawing its BLA, citing issues "related to the quality of data collection and monitoring of the pivotal clinical trials by the clinical research organization [ ] contracted to manage the trials."

VI. POURHASSAN SELLS MILLIONS OF DOLLARS OF CYTODYN STOCK WHILE IN POSSESSION OF MATERIAL NONPUBLIC INFORMATION ABOUT CYTODYN'S BLA SUBMISSION.

118. At all relevant times, CytoDyn had a policy that prohibited insider trading by all of its officers, directors, and employees (the "Insider Trading Policy").

119. Specifically, the Insider Trading Policy prohibited all of CytoDyn officers, directors, and employees who are aware of material nonpublic information related to CytoDyn from engaging in transactions in the securities of CytoDyn.

120. Among other transactions, the Insider Trading Policy expressly covered the sale of CytoDyn common stock.

121. The Insider Trading Policy applied to Pourhassan, who was both an officer and director of CytoDyn.

122. The Insider Trading Policy stated that material information is "information for which there is a substantial likelihood that a reasonable investor would consider such information important in making his or her investment decisions, or information that could be reasonably expected to affect the price of a company's securities, whether it is positive or negative."

123. The Insider Trading Policy further stated that "nonpublic" information is "information which has not been made available to investors generally."

124. The Insider Trading Policy warned that the penalties for the purchase or sale of CytoDyn securities while aware of material nonpublic information are "severe" and include "substantial jail terms," "disgorgement of profits," "fines for the person who committed the violation of several times the profit gained or loss avoided, whether or not the person actually benefited," and "orders barring individual from serving as a director or officer of a public company."

125. Between April 30, 2020, and May 4, 2020, Pourhassan sold $15,760,909.87 worth of CytoDyn stock, the vast majority of which he acquired through the exercise of vested stock options.

126. When he sold this stock, Pourhassan knew that CytoDyn's BLA submission, which a press release had trumpeted as "complete," was not complete and, in fact, was missing key clinical datasets.

127. Over the course of just three trading days, Pourhassan sought to, and did, sell the maximum number of shares that he was permitted to sell in a *three-month* period pursuant to the volume limitations for sales by affiliates (like Pourhassan) of an issuer (like CytoDyn). These volume limitations are contained in Commission Rule 144(e) [17 C.F.R. § 230.144(e)].

128. In order to exercise these options, Pourhassan signed 12 option exercise forms.

129. Pourhassan confirmed in each such form that his sales of the shares he was to acquire by exercising these options would comply with the Insider Trading Policy.

130. Pourhassan also signed a Form 144 for the stock he sold on April 30, 2020. In it, Pourhassan certified that he was not in possession of material nonpublic information.

131. By at least April 23, 2020, Pourhassan caused others at CytoDyn to prepare the paperwork that would enable him to exercise these options and place these trades.

132. Pourhassan began discussing his planned options exercise with his brokers on or about April 28, 2020.

133. On April 30, 2020, Pourhassan exercised 11 sets of options to acquire 5,381,167 shares of CytoDyn stock, which represented a nearly 1,700% increase in his holdings of CytoDyn stock.

134. One of the options that Pourhassan exercised on April 30, 2020, was for the 2,000,000 shares with an exercise price of $0.63 that he received in December 2019 and which had just vested upon the filing of the BLA submission three days before.

135. The same day, Pourhassan sold 2,219,837 shares of CytoDyn stock for proceeds of $7,838,688.41.

136. On May 1, 2020, Pourhassan sold an additional 1,399,685 shares of CytoDyn stock for proceeds of $4,569,131.71.

137. The following Monday, May 4, 2020, Pourhassan exercised an additional option to acquire 30,933 shares of CytoDyn stock.

138. The same day, Pourhassan sold 1,201,652 shares of CytoDyn stock for proceeds of $3,353,089.74.

139. Of the approximately $15.8 million that Pourhassan's sales of CytoDyn stock generated, he paid a total of approximately $11 million back to CytoDyn—$3,792,058.00 to pay the exercise prices of the options and $7,247,450.63 in tax payments.

140. Accordingly, Pourhassan netted a profit of $4,721,401.24 on these sales.

VII. KAZEMPOUR SELLS HUNDREDS OF THOUSANDS OF DOLLARS OF CYTODYN STOCK BEFORE THE FDA'S REFUSE TO FILE LETTER.

141. On April 28, 2020, the day after CytoDyn issued its materially false press release concerning a "completed" BLA submission, Kazempour emailed CytoDyn's chief financial officer and indicated that he wanted to exercise a previously-issued warrant so that he could obtain and sell 150,000 shares of CytoDyn common stock.

142. Kazempour followed up with another email to CytoDyn's chief financial officer on May 15, 2020, asking if Kazempour could pay the exercise price for those 150,000 warrant shares.

143. Thereafter, Kazempour paid CytoDyn $84,750 to obtain the shares (i.e., an exercise price of $0.565 per share) and deposited the shares into his brokerage account.

144. On June 9 and 10, 2020, Kazempour sold these 150,000 shares of CytoDyn stock for total proceeds of $427,475.67.

145. Accordingly, Kazempour received a pre-tax profit of $342,725.67 from his sales of these shares.

146. At the time of these sales, Kazempour knew that the BLA submission he had filed was not complete and expected the FDA to issue a Refuse to File letter, which it ultimately did a month later.

VIII. CYTODYN AND POURHASSAN MAKE ADDITIONAL MATERIALLY FALSE AND MISLEADING STATEMENTS ABOUT COVID-19 TRIALS IN 2021.

147. In addition to the press releases Pourhassan caused CytoDyn to issue concerning its BLA submission for the use of leronlimab as a possible treatment for HIV, Pourhassan also was responsible for materially false and misleading statements related to the company's clinical trials for the use of leronlimab as a possible treatment for COVID-19.

148. CytoDyn obtained permission from the FDA to conduct clinical trials to treat COVID-19 in early 2020. Amarex conducted those trials.

149. In or about January 2021 CytoDyn obtained the results from one of its clinical trial, which was called the "CD12 Trial."

150. The CD12 Trial did not meet any of its primary or secondary "endpoints"—that is, the specific objectives of the trial identified before its initiation.

151. Though companies typically prepare lengthy reports to the FDA concerning clinical trial results, CytoDyn prepared and submitted to the FDA an "executive summary" of the CD12 Trial on February 16, 2021.

152. At Pourhassan's direction, Amarex included "subgroup" analysis in the executive summary—that is, analysis of smaller groups of subjects as opposed to the full trial group—in

order to make the results of the CD12 Trial sound better than they were. CytoDyn Employee-2 was pressured to include this information by Pourhassan.

153. On February 18 and 25, 2021, the FDA sent letters to CytoDyn Employee-2 stating that it did not agree with CytoDyn's conclusions related to the benefits of leronlimab for the treatment of COVID-19 patients based on its subgroup analysis.

154. Nevertheless, on March 8, 2021, CytoDyn publicly announced the results of the CD12 Trial by emphasizing the same subgroup analysis that had been rejected by the FDA.

155. Further, at Pourhassan's direction, on March 8 and March 30, 2021, CytoDyn issued press releases that suggested that the CD12 Trial had demonstrated that leronlimab decreased mortality for severe-to-critically ill patients with COVID-19 through the use of this same subgroup analysis.

156. In reality, as Pourhassan knew from CytoDyn Employee-2 and the FDA's correspondence, the CD12 Trial had not met its key endpoints, which made touting subgroup analysis, which was not the point of the trial, misleading.

157. Pourhassan reviewed and approved the issuance of these press releases by CytoDyn.

158. CytoDyn issued both March 2021 press releases before the markets opened each day and the releases resulted in significantly higher trading volume.

159. On March 8, 2021, the trading volume that day was approximately 21,383,800 shares, or 460% higher than the trading volume the prior trading day.

160. On March 30, 2021, the trading volume was approximately 10,878,600 shares, or 330% higher than the trading volume the prior trading day.

161. On April 14, 2021, CytoDyn filed a Form 10-Q with the Commission that stated that the results of the CD12 Trial were reported in the Form 8-K it had filed on March 8, 2021.

162. Ultimately, on May 17, 2021, the FDA put out a public statement about leronlimab in order to correct the misleading information in CytoDyn's press releases.

163. In that statement, the FDA clarified that, based on these same 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."

164. The FDA further explained in its statement that CytoDyn's press releases had communicated differences in "small subgroups" from the CD12 trial, which has "well-established limitations, especially in the context of a clinical trial that has failed to show a benefit in the overall study population."

165. In addition to causing CytoDyn to issue false and misleading press releases, Pourhassan participated in video "interviews" by a company called Proactive Media.

166. Proactive Media describes itself as a "financial media portal" that provides news, commentary, and analysis on hundreds of public and private companies.

167. Pourhassan retained Proactive Media on behalf of CytoDyn and CytoDyn paid Proactive Media at least $25,000 for its services.

168. For each of these "interviews," Pourhassan would provide a script to the interviewer with questions to ask and talking points from recent CytoDyn press releases. Pourhassan would then use the video as a way to promote CytoDyn's stock to investors or potential investors.

169. These videos were posted both on Proactive Media's website and on its channel on YouTube.com. Certain of the videos, including the video described below, were also made available via hyperlink from CytoDyn's corporate website.

170. In one of these videos, which was posted on or about September 22, 2021, Pourhassan made a number of misleading statements that suggested leronlimab had been established as safe and effective for the treatment of COVID-19. For example, Pourhassan stated the following in the video:

a. "In the United States, we did a trial of 394 patients which included severe and critically ill population. In the critically-ill population, our results were really strong."

b. "Our critically-ill population that we did in the United States when we gave a dose of leronlimab, the survival rate was 78%. Once we gave them another dose, the survival rate went up to 82%."

c. "Imagine, if 78% went to 82, the next one would be maybe 88, and then 95. I am making up numbers, but if it goes to that kind of numbers, if it just follows the same pattern what we learned, this is going to be the most fantastic results anybody could ever imagined to have. Now I'm not saying that's what we're going to get, but I'm saying that's what the results are showing."

d. "The primary endpoint . . . is the discharge, the rate of patients who get on ventilator and get discharged. That endpoint was 166% better in our trial that we did in the United States versus placebo. 166%."

171. In reality, as Pourhassan well knew, he had again mischaracterized CytoDyn's COVID-19 clinical trials, which the FDA had previously told him and the public just four

months earlier (in its statement on May 17, 2021) "do not support the clinical benefit of leronlimab for the treatment of COVID-19."

172. On February 11, 2022, the FDA issued a warning letter to CytoDyn about this video.

173. In the letter, the FDA stated that the September 2021 video "represents in a promotional context that leronlimab, an investigational new drug, is safe and effective for the purpose for which it is being investigated or otherwise promotes the drug."

174. The FDA concluded that, "[a]s a result, leronlimab is misbranded under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and is in violation of section 301(a) of the FD&C Act."

175. The FDA further advised that "the video is concerning from a public health perspective because it suggests that leronlimab provides a clinical benefit to individuals with [COVID-19]," despite the fact that it "has not been approved or authorized by the FDA and whose safety and efficacy has not yet been established."

FIRST CLAIM FOR RELIEF
Violations of Securities Act Section 17(a)
(Pourhassan and Kazempour)

176. The Commission re-alleges and incorporates by reference here the allegations in paragraphs 1 through 175.

177. Defendants, directly or indirectly, singly or in concert, in the offer or sale of securities and by the use of the means or instruments of transportation or communication in interstate commerce or the mails, (i) knowingly or recklessly have employed one or more devices, schemes or artifices to defraud, (ii) knowingly, recklessly, or negligently have obtained money or property by means of one or more untrue statements of a material fact or omissions of

a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and/or (iii) knowingly, recklessly, or negligently have engaged in one or more transactions, practices, or courses of business which operated or would operate as a fraud or deceit upon the purchaser.

178. By reason of the foregoing, Defendants, directly or indirectly, singly or in concert, have violated and, unless enjoined, will again violate Securities Act Section 17(a) [15 U.S.C. § 77q(a)].

SECOND CLAIM FOR RELIEF
Violations of Exchange Act Section 10(b) and Rule 10b-5 Thereunder
(Pourhassan)

179. The Commission re-alleges and incorporates by reference here the allegations in paragraphs 1 through 175.

180. Pourhassan, directly or indirectly, singly or in concert, in connection with the purchase or sale of securities and by the use of means or instrumentalities of interstate commerce, or the mails, or the facilities of a national securities exchange, knowingly or recklessly has (i) employed one or more devices, schemes, or artifices to defraud, (ii) made one or more untrue statements of a material fact or omitted to state one or more material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and/or (iii) engaged in one or more acts, practices, or courses of business which operated or would operate as a fraud or deceit upon other persons.

181. By reason of the foregoing, Pourhassan, directly or indirectly, singly or in concert, has violated and, unless enjoined, will again violate Exchange Act Section 10(b) [15 U.S.C. § 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. § 240.10b-5].

THIRD CLAIM FOR RELIEF
Violations of Exchange Act Section 10(b) and Rules 10b-5(a) and (c) Thereunder
(Kazempour)

182. The Commission re-alleges and incorporates by reference here the allegations in paragraphs 1 through 175.

183. Kazempour, directly or indirectly, singly or in concert, in connection with the purchase or sale of securities and by the use of means or instrumentalities of interstate commerce, or the mails, or the facilities of a national securities exchange, knowingly or recklessly has (i) employed one or more devices, schemes, or artifices to defraud, and/or (ii) engaged in one or more acts, practices, or courses of business which operated or would operate as a fraud or deceit upon other persons.

184. By reason of the foregoing, Kazempour, directly or indirectly, singly or in concert, has violated and, unless enjoined, will again violate Exchange Act Section 10(b) [15 U.S.C. § 78j(b)] and Rules 10b-5(a) and 10b-5(c) thereunder [17 C.F.R. §§ 240.10b-5(a) and 240.10b-5(c)].

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests that the Court enter a Final Judgment:

I.

Permanently enjoining Defendant Pourhassan, his agents, servants, employees, and attorneys and all persons in active concert or participation with any of them from violating, directly or indirectly, Securities Act Section 17(a) [15 U.S.C. § 77q(a)] and Exchange Act Section 10(b) [15 U.S.C. § 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. § 240.10b-5];

II.

Permanently enjoining Defendant Kazempour, his agents, servants, employees, and attorneys and all persons in active concert or participation with any of them from violating, directly or indirectly, Securities Act Section 17(a) [15 U.S.C. § 77q(a)] and Exchange Act Section 10(b) [15 U.S.C. § 78j(b)] and Rules 10b-5(a) and 10b-5(c) thereunder [17 C.F.R. §§ 240.10b-5(a) and 240.10b-5(c)];

III.

Ordering Defendants to disgorge all ill-gotten gains they received directly or indirectly, with prejudgment interest thereon, as a result of the alleged violations, pursuant to Exchange Act Sections 21(d)(5) and 21(d)(7) [15 U.S.C. §§ 78u(d)(5), and 78u(d)(7)];

IV.

Ordering Defendants to pay civil monetary penalties under Securities Act Section 20(d) [15 U.S.C. § 77t(d)] and Exchange Act Section 21(d)(3) [15 U.S.C. § 78u(d)(3)];

V.

Ordering Pourhassan to pay a civil money penalty pursuant to Exchange Act 21A(a) [15 U.S.C. § 78u-1(a)];

VI.

Permanently prohibiting Defendants from serving as an officer or director of any company that has a class of securities registered under Exchange Act Section 12 [15 U.S.C. § 78l] or that is required to file reports under Exchange Act Section 15(d) [15 U.S.C. § 78o(d)], pursuant to Securities Act Section 20(e) [15 U.S.C. § 77t(e)] and Exchange Act Section 21(d)(2) [15 U.S.C. § 78u(d)(2)];

VII.

Granting any other and further relief this Court may deem just and proper.

Dated: New York, New York
December 20, 2022

/s/ Thomas P. Smith, Jr.

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