The Honorable Benjamin H. Settle

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

BRIAN JOE COURTER, COURTER AND SONS LLC, DIANE M. HOOPER, THOMAS MCGEE, and CANDRA E. EVANS, Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

v.

CYTODYN INC., NADER Z. POURHASSAN, MICHAEL MULHOLLAND, and SCOTT A. KELLY,

Defendants.

No. C21-5190 BHS

Complaint—Class Action

AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY DEMAND

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Court-appointed Lead Plaintiff Brian Joe Courter and Courter and Sons LLC ("Lead Plaintiff") and Named Plaintiffs Diane M. Hooper, Thomas McGee, and Candra E. Evans (collectively, "Plaintiffs") by and through their attorneys, and on behalf of all others who purchased or otherwise acquired the common stock of CytoDyn Inc. ("CytoDyn" or the "Company") between March 27, 2020 and May 17, 2021 (the "Class Period"), and were damaged thereby (the "Class"), allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief are based upon, inter alia, the ongoing investigation conducted by and through their attorneys, which included, among other things, a review and analysis of: (i) public filings with the United States Securities and Exchange Commission ("SEC") made by CytoDyn; (ii) research reports by securities and financial analysts and investors; (iii) articles published by the news media; (iv) transcripts of CytoDyn's calls with analysts and investors; (v) CytoDyn investor presentations, press releases, and reports; (vi) online media reports including interviews with CytoDyn Chief Executive Officer ("CEO"), Defendant Nader Z. Pourhassan ("Pourhassan"), among others; (vii) analyses of CytoDyn's securities movement and price and volume data; (viii) pleadings, filings, evidentiary matter, and court orders in other litigation involving CytoDyn or the Individual Defendants (defined below); and (ix) other publicly available material and data identified herein. Court-appointed Lead Counsel's investigation into the factual allegations contained herein is ongoing. Many of the relevant facts are known only by the Defendants (defined below) or are exclusively within their custody, possession, or control. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for further investigation and/or discovery.

I. INTRODUCTION[1]

1. This federal securities class action arises from: (i) Defendants' materially false and misleading statements concerning (a) CytoDyn's submission to the United States Food and

[1] Throughout this Complaint, all emphasis is added unless otherwise noted.

Drug Administration ("FDA") of a Biologics License Application ("BLA") for the use of its only drug, leronlimab, to treat HIV, and (b) the use of leronlimab to treat patients diagnosed with COVID-19 and, separately; (ii) Defendants' scheme to promote leronlimab and the likelihood of FDA approval of its use to treat COVID-19—which Defendants exploited to, among other things, dump 7.8 million shares at inflated prices, for more than $30 million in proceeds.

2. CytoDyn is a pre-revenue biotechnology company. Before the Class Period, CytoDyn was considered a "microcap" public company and its common stock, which traded over-the-counter ("OTC") under the ticker "CYDY," a penny stock. Since October 2012, CytoDyn has focused on the development and commercialization of a single drug, leronlimab, and has attempted to identify applications for it including in the treatment of HIV, over twenty cancer indications, and most recently, COVID-19. As of the date of this Complaint, CytoDyn has yet to announce that any regulatory agency has approved the marketing and sale of leronlimab for any indication. As a result, the Company earns no revenues and remains effectively insolvent while facing: (i) millions of dollars in unpaid invoices to its vendors, including $14 million owed to Amarex Clinical Research, LLC ("Amarex"), CytoDyn's Class Period Clinical Research Organization ("CRO"); (ii) significant payments under various agreements, including tens of millions owed to Samsung BioLogics Co., Ltd. ("Samsung") for the manufacture of leronlimab; and (iii) at least one unpaid arbitration award of more than $6 million tied to the Company's refusal to comply with its merger agreement with ProstaGene, LLC ("ProstaGene").

3. CytoDyn's President and CEO, Defendant Pourhassan, and his enablers and co-conspirators, Defendants Scott A. Kelly ("Kelly") and Michael Mulholland ("Mulholland"), the Company's Chief Medical Officer ("CMO") and Chief Financial Officer ("CFO"), respectively, had complete control of CytoDyn during the Class Period. As explained herein, prior to the start of the Class Period, Pourhassan, with Kelly's assistance, pushed out or terminated any CytoDyn executive, member of its board of directors (the "Board"), or vendor that attempted to block

Pourhassan from engaging in wasteful, fraudulent, and potentially illegal conduct related to Pourhassan's compensation and his public statements to investors.

4. For instance, after CytoDyn's Board told Pourhassan in late 2018 and early 2019 that there needed to be a more rigorous process in place to ensure the accuracy of public statements, Pourhassan tried to fire a Lowenstein Sandler LLP ("Lowenstein") attorney seeking to implement that process. Pourhassan did not initially succeed because of the intercession of CytoDyn's then-CMO, Dr. Richard Pestell ("Dr. Pestell") and then-Board member Carl Dockery ("Dockery"); however, after Pourhassan, with Defendant Kelly's assistance, terminated Dr. Pestell for cause and pushed Dockery off the Board, CytoDyn replaced Lowenstein with internal general counsel in January 2020, leaving Pourhassan free to issue any public statements he wished without oversight or interference from CytoDyn's Board or Lowenstein.

5. Defendant Pourhassan also used his control of CytoDyn, with the assistance of Defendant Kelly, to award himself an outsized compensation package for fiscal years 2020 ("FY20") and 2021 ("FY21"),[2] despite CytoDyn's lack of solvency. Defendants Pourhassan and Kelly, with the acquiescence of Mulholland, also awarded themselves millions of suspiciously timed options and warrants in December 2019 and January 2020. Pourhassan brazenly exercised and sold 4.8 million options/warrants, some of which he improperly granted himself in December 2019, over three trading days during the Class Period while CytoDyn's stock price was inflated by Defendants' fraudulent misstatements and scheme, netting himself millions of dollars in proceeds before he was forced to forfeit these awards as part of a settlement with a special committee of CytoDyn's Board. During a hearing before the Court of Chancery of the State of Delaware ("Delaware Chancery Court") overseeing that settlement, the Honorable Paul A. Fioravanti, Jr. described Pourhassan as "the mastermind of these awards," and concluded that

[2] CytoDyn's fiscal year ("FY") runs from June 1 to May 31. CytoDyn's fiscal quarters run as follows: June 1 to August 31 ("1Q"), September 1 to November 30 ("2Q"), December 1 to February 28 ("3Q"), and March 1 to May 31 ("4Q").

he was "deeply troubled by the behavior of the defendants [including Pourhassan and Kelly] in approving these awards" and "[b]ased upon the record [before the court], ***this strikes me as a case of unmitigated greed***."

6. **CytoDyn's HIV BLA**. Prior to the start of the Class Period, CytoDyn's only chance to earn ***any*** revenues, let alone profits, hinged on the Company's ability to obtain FDA approval to market and sell leronlimab to treat HIV patients. After months of delays, Defendants announced that CytoDyn had submitted to the FDA a purportedly "complete" HIV BLA on or around April 27, 2020. Defendant Pourhassan described the supposedly "complete" HIV BLA submission as "a monumental achievement for our Company" on April 27, 2020, telling investors "the BLA is submitted" and "[t]he BLA got filed." On the news, an analyst covering CytoDyn increased its valuation of the Company by $700 million and its target price per CytoDyn share to $4.00, a 300% increase over the pre-Class Period trading price.

7. The undisclosed reality was far different. Beginning in December 2018, the FDA had repeatedly met and corresponded with Defendants regarding the content of CytoDyn's HIV BLA, giving the Company clear guidance as to what information, data, and analyses must be included in a "complete" HIV BLA. Prior to April 2020, the CEO of CytoDyn's CRO, Amarex, Kazem Kazempour ("Kazempour"), repeatedly warned Defendant Pourhassan that CytoDyn's HIV BLA was incomplete. Nevertheless, in a non-public April 14, 2020 e-mail to Kazempour, Pourhassan directed Amarex to file CytoDyn's HIV BLA by April 2020 "***even if we are short in no matter what portion of whatever it is that we are short***" because the Company's stock price had declined and Pourhassan was "getting bombarded by investors who are very frustrated with me and CytoDyn." This jaw-dropping e-mail became public only recently through litigation between Amarex and CytoDyn. Simply put, the BLA was grossly inadequate, but Defendants had filed it anyway to lift CytoDyn's flagging stock price.

8. Moreover, Defendant Pourhassan knew that time was running out for him to cash-in on the options and warrants he and Defendant Kelly had improperly granted themselves and

Defendant Mulholland in December 2019, the vesting of which was tied to CytoDyn's filing of a complete HIV BLA with the FDA. Following several non-public demand letters from irate shareholders regarding the December 2019 awards, on April 24, 2020, three former Board members, Dockery, Gregory A. Gould ("Gould"), and Anthony Caracciolo ("Caracciolo") sued Pourhassan and Kelly, among others, in Delaware Chancery Court derivatively on behalf of the Company with respect to the awards. With the December 2019 awards vesting on or around April 27, 2020 based on CytoDyn's submission of a purportedly "complete" HIV BLA, and a meritorious lawsuit looming, Pourhassan immediately exercised 50% of the options/warrants he received as part of the December 2019 Awards and sold at least 70% of the resulting shares for millions of dollars in proceeds.

9. Following Defendant Pourhassan's and Kelly's stock sales, CytoDyn issued a May 4, 2020 press release which disclosed that, in fact, the HIV BLA submitted on or around April 27, 2020 was not complete and would not be complete until May 11, 2020. In response to the news, the price of CytoDyn's common stock declined 13% on significant trading volume. Undeterred, the Company subsequently announced that it had submitted a purportedly complete HIV BLA to the FDA on May 11, 2020.

10. Defendants could not avoid the truth much longer. On July 8, 2020, Defendants received from the FDA a non-public letter in which the FDA refused to file CytoDyn's May 11, 2020 HIV BLA resubmission because it "d[id] not contain all pertinent information and data needed to complete a substantive review" (the "RTF Letter"). Over twenty pages long, the RTF Letter explained in painstaking detail the "numerous omissions and inadequacies" that were "severe" enough "to render the [HIV BLA] incomplete." The FDA rarely issues RTF letters—only in response to drug approval applications that are so facially deficient in their contents and substance that they do not merit any actual review by the agency.

11. On July 13, 2020, CytoDyn publicly disclosed to investors that it had received the RTF Letter. With this admission, the market now understood that the Company's April 2020

HIV BLA submission and May 11, 2020 resubmission were both deeply flawed and that FDA approval of the marketing and sale of leronlimab would now be delayed indefinitely. Leronlimab, in other words, was nowhere near generating revenues for CytoDyn. In reaction to the news, the stock price declined nearly 22%. To date, CytoDyn has not resubmitted a complete HIV BLA.

12. **COVID-19**. The COVID-19 pandemic separately presented Defendants with a golden opportunity exploit their control of CytoDyn and its Board to execute a fraudulent stock promotion scheme. Having removed the only real check on the accuracy of their statements by January 2020 (e.g., Dr. Pestell, Dockery, and Lowenstein), Defendants created a buying frenzy for CytoDyn shares, issuing more than 100 COVID-19 related press releases during the Class Period, and paying promotional websites for a platform through which they could speak to investors on a near daily basis, reiterating and amplifying their hype. A significant amount of the information Defendants provided to investors concerning COVID-19 was never filed with the SEC and, as explained in detail below, many of the events or milestones Defendants touted as part of their promotional efforts never came to fruition—a tell-tale sign of "microcap fraud" according to the SEC.

13. Through this blizzard of promotion, Defendants constructed a façade that: (i) leronlimab was safe and effective for the treatment of COVID-19; (ii) the results of Phase 2 (CD10) and Phase 2b/3 (CD12) Trials (defined herein) demonstrated that leronlimab was effective in treating COVID-19; (iii) U.S., U.K., and Canadian (among other countries) regulatory authorization to market and sell leronlimab to treat COVID-19 was imminent; and (iv) CytoDyn would soon "uplist" to the NASDAQ exchange. Defendants' fraudulent stock promotion scheme pumped up the price of the Company's shares such that CytoDyn's stock price and market capitalization increased nearly 900%, with shares trading as high as $10.00 during the Class Period and CytoDyn's market capitalization reaching nearly $5 billion. Incredibly, Defendants were able to generate historic increases in the Company's stock price and

marketing capitalization without having an FDA-approved drug or, indeed, any revenues (let alone profits) to speak of.

14. Defendants all cashed-in on their fraudulent stock promotion scheme. As noted above, Defendant Pourhassan sold millions of dollars of CytoDyn shares over three trading days beginning on April 30, 2020. For his part, Defendant Mulholland exercised and sold more than 1.8 million shares at weighted average prices 500% higher than CytoDyn's pre-Class Period stock price for proceeds of more than $10 million over four trading days in December 2020. Defendant Pourhassan also negotiated a new employment agreement in June 2020, giving him a base salary of $1,000,000 and at target bonus of $1,000,000, both of which he received for FY21 despite the fact that CytoDyn was insolvent and had yet to obtain regulatory approval to market or sell leronlimab for any indication in any country, including the U.S.

15. Defendants' fraudulent stock promotion scheme began to unravel on Friday, March 5, 2021. On that date, after the conclusion of trading, CytoDyn announced disappointing results from its Phase 2b/3 Trial (CD12) for critical or severe COVID-19 patients. Over that weekend, CytoDyn issued several more press releases discussing the results. CytoDyn's stock price declined more than 28% on the next trading day, March 8, 2021, on the news.

16. After the conclusion of trading on March 8, 2021, Defendants held a conference call to discuss the Phase 2b/3 Trial (CD12) and filed with the SEC an executive summary of the results on a Form 8-K signed by Defendant Mulholland. During the conference call, Defendants admitted that the Phase 2b/3 Trial had not reached its primary endpoint. Following this news, the next day, CytoDyn's stock price declined more than 19% further, on significant trading volume.

17. Undeterred, Defendants sought to maintain their stock promotion fraud by spinning the Phase 2b/3 Trial (CD12) results and pivoting to their purported efforts to obtain approval to sell leronlimab outside of the U.S. As part of that effort, on March 30, 2021, CytoDyn issued "further results from its CD12 trial" which supposedly consisted of a "further statistical analysis" of the same data Defendants disclosed between March 5 and March 8, 2021.

According to Defendant Pourhassan, "this new information bolsters the case for immediate use of leronlimab for critically ill [COVID-19] patients" and would be submitted to the U.S., U.K., and Canadian regulatory authorities.

18. Thereafter, on May 17, 2021, the FDA took the nearly unprecedented step of issuing a public statement on an unapproved drug. Titled, "Statement on Leronlimab," the FDA exposed Defendants' lies about the safety and efficacy of leronlimab to treat COVID-19 and the Phase 2 (CD10) and Phase 2b/3 (CD12) Trials, stating bluntly: "***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***." With respect to the trial results, the FDA confirmed that "the CD10 results indicate that most study participants experienced resolution of COVID-19 symptoms regardless of whether they received leronlimab or placebo" and the CD12 trial "failed to find any effect of the drug on the primary study endpoint . . . or on any of the secondary endpoints." In response to the FDA's statement, the price of CytoDyn's common stock declined more than 27% on heavy trading volume. CytoDyn's common stock currently trades OTC around $1.00 per share.

19. On July 30, 2021, CytoDyn disclosed that it was being investigated by both the SEC and the United States Department of Justice ("DOJ"), with CytoDyn and certain of its executives having received subpoenas seeking testimony and/or records concerning the Company's "public statements regarding the use of leronlimab as a potential treatment for COVID-19 and related communications with the FDA, investors, and others, and trading in the securities of CytoDyn." These investigations are ongoing.

II. JURISDICTION AND VENUE

20. The claims asserted herein arise under Sections 10(b) and 20(a), and 20A of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and 78t-1(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

21. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and under 28 U.S.C. § 1331, because this is a civil action arising under the laws of the United States.

22. Venue is proper in this District pursuant to28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information to the investing public, occurred in substantial part in this District. Additionally, CytoDyn's principal executive offices are located within this District.

23. In connection with the acts, transactions, and conduct alleged in this Complaint, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mails, interstate telephone communications, and the OTC Markets Group's OTCQB Venture Market.

III. PARTIES AND RELEVANT NON-PARTIES

A. Plaintiffs

24. Lead Plaintiff Brian Joe Courter is a resident of Missouri. He participates in this litigation both individually and on behalf of Courter and Sons LLC, a real estate company. As set forth in the certification attached hereto as Exhibit A, Lead Plaintiff purchased or otherwise acquired CytoDyn common stock at artificially inflated prices during the Class Period and was damaged as a result of Defendants' alleged misconduct.

25. Named Plaintiff Diane M. Hooper ("Hooper") is a resident of Illinois. As set forth in the certification attached hereto as Exhibit B, Hooper purchased or otherwise acquired CytoDyn common stock at artificially inflated prices during the Class Period and was damaged as a result of Defendants' alleged misconduct.

26. Named Plaintiff Thomas McGee ("McGee") is a resident of Connecticut. As set forth in the certification attached hereto as Exhibit C, McGee purchased or otherwise acquired

CytoDyn common stock at artificially inflated prices during the Class Period and was damaged as a result of Defendants' alleged misconduct.

27. Named Plaintiff Candra E. Evans ("Evans") is a resident of Nevada. As set forth in the certification attached hereto as Exhibit D, Evans purchased or otherwise acquired CytoDyn common stock at artificially inflated prices during the Class Period and was damaged as a result of Defendants' alleged misconduct.

B. Defendants

28. Defendant CytoDyn is a publicly-traded biotechnology company. Headquartered in Vancouver, Washington, and incorporated in Delaware, CytoDyn is focused on the development and commercialization of a drug named "leronlimab" which has long been promoted as a potential therapy for various indications, but has never received regulatory approval to be marketed. As of August 14, 2019, August 14, 2020, and July 30, 2021, CytoDyn had ten (10), nineteen (19), and twenty-four (24) full-time employees, respectively. CytoDyn's common stock trades on the OTCQB under the ticker symbol "CYDY."

29. Defendant Pourhassan has served as CytoDyn's CEO, President, and as a Board member since 2012. He was appointed to the CytoDyn Board in September 2012, and became CytoDyn's President and CEO in December 2012, following his service as interim President and CEO for the preceding three months. Prior to his appointment as President and CEO, Pourhassan was CytoDyn's Chief Operating Officer from May 2008 until June 2011, and Managing Director of Business Development from June 2011 until September 2012.

30. Defendant Michael Mulholland ("Mulholland") served as CytoDyn's CFO, Treasurer, and Corporate Secretary from December 2012 until November 2019, when he became Senior Vice President of Finance and Executive Advisor to the CEO. On April 23, 2020, he became interim CFO and was formally named CFO on May 27, 2020.

31. Defendant Scott A. Kelly ("Kelly") has been a member of the Board of CytoDyn since April 2017. In December 2018, he was named Chairman of the Board. In July 2019,

Dr. Kelly was named as CytoDyn's Chief Science Officer. On April 13, 2020, CytoDyn announced that Kelly was appointed as CMO and Head of Business Development.

32. Defendants Pourhassan, Mulholland, and Kelly are referred to collectively as the "Individual Defendants."

33. During the Class Period, the Individual Defendants, as senior officers and/or directors of CytoDyn, were privy to confidential, proprietary, and material adverse non-public information concerning the Company, its operations, finances, financial condition, and present and future business prospects via access to internal corporate documents, conversations, and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or were deliberately reckless in disregarding that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

34. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior officers and/or directors, were "controlling persons" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of CytoDyn's business.

35. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases, and presentations to securities analysts and media, and through them, to the investing public. The Individual Defendants were provided with copies of the Company's reports and publicly disseminated documents alleged herein to be misleading, prior to or shortly after their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected.

36. As senior officers and/or directors and as controlling persons of a publicly traded company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and governed by the federal securities laws, the Individual Defendants had a duty to disseminate promptly accurate and truthful information with respect to CytoDyn's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings, and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so the market price of CytoDyn common stock would be based on truthful and accurate information. The Individual Defendants' material misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

37. The Individual Defendants also are liable under Section 10(b) and Rule 10b-5(a & c) as participants in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of CytoDyn's publicly traded common stock by disseminating materially false and misleading statements and/or concealing material adverse facts.

C. Relevant Non-Parties

38. **CEORoadshow.com**. CEORoadshow.com is owned and operated by Capital Markets Connect, LLC. According to its website, CEORoadshow "provides Investor Media, News, Research and IR Services" including "'Investor Pitches' videos, 'Investor Updates' videos, 'CEORoadshow Watchlist' videos, and other CEORoadshow Videos, Investor Media, publications or presentations," and "content on CEORoadshow.com.com [sic]." Capital Markets Connect, LLC "is an entity engaged in the business of public relations and investor relations and has been hired by certain Companies to increase investor awareness . . . ." CytoDyn listed Michael Elliot d/b/a CEO Live (a/k/a CEORoadshow.com) as a "third party provider[] . . . engaged by the Company . . . to provide investor relations services, public relations services, marketing, brand awareness, consulting, stock promotion, or any other related services to the

Company" in CytoDyn's OTCQB certifications. CytoDyn has been a paying client of CEORoadshow since October 2018.

39. **Emerging Growth**. Emerging Growth is affiliated with Global Discovery Group. Global Discovery Group, Inc.'s "services" include "Stock Marketing" or "creative media campaigns [that] target the shareholders of your blue chip public company peers." CytoDyn listed Global Discovery Group, Inc. as a "third party provider[] . . . engaged by the Company . . . to provide investor relations services, public relations services, marketing, brand awareness, consulting, stock promotion, or any other related services to the Company" in CytoDyn's OTCQB certifications. A CytoDyn-specific disclosure on Emerging Growth's website states that "EG has received [$12,500] and can receive an additional [$17,500] in consideration for its work with CytoDyn, Inc." A different disclosure statement on the same website claims that "[c]ompanies profiled on EG.com have paid Emerging Growth a minimum of $500.00 for each post." With more than 70 posts between 2018 and the end of the Class Period, CytoDyn may have paid upwards of $35,000 to Emerging Growth.

40. **Proactive Investors LLC**. CytoDyn listed Proactive Investors as a "third party provider[] . . . engaged by the Company . . . to provide investor relations services, public relations services, marketing, brand awareness, consulting, stock promotion, or any other related services" in CytoDyn's OTCQB certifications. Proactive Investors "receives either monetary or securities compensation for [its] services." Specifically, "[i]n exchange for publishing services rendered by [Proactive Investors] on behalf of any issuer named on the Site, including the promotion by the [Proactive Investors] of the issuer in any Content on the Site, [Proactive Investors] receives" an annual payment from the issuer of $25,000. CytoDyn was a client of Proactive Investors beginning no later than January 2019. Accordingly, the Company has paid Proactive Investors at least $75,000 in fees for "publishing services."

41. **RedChip Companies, Inc.** CytoDyn lists RedChip Companies, Inc. as a "third party provider[] . . . engaged by the Company . . . to provide investor relations services, public

relations services, marketing, brand awareness, consulting, stock promotion, or any other related services" in CytoDyn's OTCQB certifications. Beginning in February 2020, CytoDyn agreed to pay RedChip Companies, Inc. a $20,000 quarterly cash fee for RedChip's "investor awareness services." CytoDyn remained a client of RedChip Companies, Inc. through at least November 3, 2020, suggesting that the Company paid RedChip Companies, Inc. at least $60,000 for its services during 2020.

42. **Wall Street Reporter**. Jack Marks ("Marks")[3] launched the current incarnation of the Wall Street Reporter in 1997 "as an internet site with a focus on CEO interviews." According to its website, Wall Street Reporter is "a leading online, market news provider that brings current news and market insight to investors and gives investors' direct access to CEO's of promising, publicly-traded companies." CytoDyn listed Wall Street Reporter as a "third party provider[] . . . engaged by the Company . . . to provide investor relations services, public relations services, marketing, brand awareness, consulting, stock promotion, or any other related services to the Company" in CytoDyn's OTCQB certifications. CytoDyn paid the Wall Street Reporter $9,500 every three months beginning no later than early 2019 for its "marketing distribution program," which "include[d] featured visibility in SPOTLIGHT, LEADERS, FEATURED STOCKS, NEWSMAKERS, and weekly highlight in e-mail newsletter." Beginning no later than the start of the Class Period, CytoDyn also paid Wall Street Reporter $18,500 every three months for its "Next SuperStock Conference Presenters/ 3 month Premium Visibility distribution" package. On information and belief, these payments totaled $178,000 in payments from March 2019 to July 2021, nearly 80% of which were incurred during the Class Period.

[3] Marks was sued by the SEC in 1998 "for disseminating information about stocks on their website, Stock-Line.com, without fully and accurately disclosing that the featured companies had paid for the touts." Marks ultimately "consented to the entry of an order permanently enjoining [him] from violations of Section 17(b)."

IV. SUBSTANTIVE ALLEGATIONS OF DEFENDANTS' FRAUD

A. CytoDyn's Financial Prospects and Potential for Future Earnings Are Dependent on Regulatory Approval of Leronlimab

43. CytoDyn, a late-stage biotechnology company, is focused on the development and commercialization of a *single* drug, leronlimab, a/k/a PRO 140 or Vyrologix. Before and during the Class Period, Defendants touted leronlimab as a potential treatment for patients suffering from various medical conditions, including HIV, COVID-19, and certain cancers. As of the date of this Complaint, the FDA has not approved CytoDyn to market or sell leronlimab for any indication. As a result, CytoDyn has never earned any revenue and, therefore, has yet to recognize any profits.

44. According to CytoDyn, leronlimab is "a monoclonal antibody C—C chemokine receptor type 5 ('CCR5') receptor antagonist . . . . The target of leronlimab is the immunologic receptor CCR5. The CCR5 receptor is a protein located on the surface of various cells including white blood cells and cancer cells. On white blood cells, it serves as a receptor for chemical attractants called chemokines." Chemokines are a family of chemoattractant cytokines (small proteins secreted by cells that influence the immune system) which play a vital role in cell migration through venules from blood into tissue and vice versa, and in the induction of cell movement in response to a chemical (chemokine) gradient by a process known as chemotaxis. **"**The CCR5 receptor has been identified as a target in HIV, GvHD (graft-versus-host disease), NASH, cancer metastasis, transplantation medicine, multiple sclerosis, traumatic brain injury, stroke recovery, and a variety of inflammatory conditions, including potentially COVID-19."

45. Leronlimab is a type of drug known as a "biologic," meaning it is derived from living material as opposed to synthesized in a lab. According to the FDA, "[b]iological products, like other drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material—

human, animal, or microorganism—are complex in structure, and thus are usually not fully characterized." And "Section 351 of the *Public Health Service (PHS) Act* defines a biological product as a 'virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings."' (Alteration in original)

B. Relevant Regulatory Framework

1. BLA and Investigational New Drug Application

46. The FDA typically requires an Investigational New Drug ("IND") Application for any clinical investigation involving administration of a drug to humans. Following initial laboratory and animal testing that show that investigational use in humans is reasonably safe, biological products like leronlimab can be studied in clinical trials in humans under an IND application. Upon receipt of an IND application, the FDA will notify the applicant of the date it received the application, and, within a set period of time, the IND applicant whether it can begin the proposed clinical research stage.

47. According to the FDA, there are three phases that apply to the pre-marketing clinical research stage.

48. During Phase 1, researchers test an experimental drug or treatment in a small group of people for the first time and the researchers evaluate the drug's safety and determine a safe dosage range. The FDA recommends 20 to 100 healthy volunteers or people with the disease/condition for study participants and a study length of several months.

49. During Phase 2, the experimental drug or treatment is given to a larger group of people to see if it is effective and to evaluate its side effects. The FDA recommends several hundred people with the disease/condition for study participants and a study length of several months to two years.

50. During Phase 3, researchers give the experimental drug or treatment to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to

commonly used treatments, and collect information that will allow experimental drug or treatment to be used safely. The FDA recommends 300 to 3,000 volunteers who have the relevant disease/condition for study participants and a study length of one to four years.

51. If the data generated by at least two Phase 1-3 trials demonstrate that the product is safe and effective for its intended use, the data are submitted to the FDA as part of a marketing application. Whereas a New Drug Application ("NDA") is used for drugs subject to the drug approval provisions of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), a BLA is required for biological products subject to licensure under the Public Health Services Act, such as leronlimab. FDA approval to market a biologic is granted by issuance of a biologics license. The ultimate issuance of a biologics license is a determination that the product, the manufacturing process, and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity and potency of the product.

52. In accordance with these and related regulations, it was necessary for CytoDyn to submit a BLA to the FDA to obtain a biologics license in order to market and sell leronlimab in the United States. FDA Form 356h specifies the requirements for a BLA: (1) applicant information; (2) product/manufacturing information; (3) pre-clinical studies; (4) clinical studies; and (5) labeling. The FDA specifies in detail the information that an applicant must submit in a BLA. A BLA applicant's Responsible Official must also acknowledge that "[t]he data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate."

53. Prior to submitting a BLA, an applicant is encouraged to discuss the planned content of the application with the appropriate review division of the FDA at a pre-BLA meeting. According to the FDA, "the pre-[]BLA meeting should be held sufficiently in advance of the planned submission of the application to allow for meaningful response to FDA feedback . . ." and "[t]he FDA and the applicant will agree on the content of a complete application for the proposed indication(s) at the pre-submission meeting." According to the FDA, "***[m]ajor***

components of the application (e.g., the complete study report of a Phase 3 clinical trial or the full study report of required long-term safety data) are expected to be submitted with the original application and are not subject to agreement for late submission."

54. Moreover, the FDA makes clear that "[a]pplications are expected to be complete, as agreed between the FDA review team and the applicant at the pre-NDA/BLA meeting, at the time of original submission of the application" and incomplete applications "***will be subject to a Refuse-to-File decision***."

55. At any time when submitting a BLA, a drug company can seek "Fast Track" designation. According to the FDA, "Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need." Such a designation "must be requested by the drug company . . . any time during the drug development process. [The] FDA will review the request and make a decision within sixty days based on whether the drug fills an unmet medical need in a serious condition."

56. If it receives a Fast Track designation for a proposed drug, an applicant is eligible for some or all of: (1) more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; (2) more frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; (3) eligibility for "Accelerated Approval and Priority Review," if certain criteria are met; and (4) "Rolling Review," which means that the applicant can submit sections of its BLA for review by the FDA, rather than waiting until every section of the BLA is completed before the entire application can be reviewed. The specific parameters of a Rolling Review must be determined with the FDA.

57. Typically, the FDA only accepts the submission of one complete section of a BLA, e.g., the entire clinical section; however, the FDA may, on occasion, "in its discretion accept less than a complete section . . . ." If an applicant submits its BLA in sections, each section "should be submitted for review in a form adequate to have been included in a complete

BLA . . . submission." Notably, "[d]rafts should not be included in a submission; if final reports need to be updated, the applicant should submit a formal amendment to the BLA . . . with the revised information." According to the FDA, "[a]t the pre-BLA . . . meeting, the [FDA] and the [applicant] should work together to clearly define the parameters of accepting an incomplete section and to determine whether FDA could conduct a meaningful review of the submission before receiving the missing information."

58. After the BLA is submitted, the FDA conducts a review, generally within sixty days, to determine whether the BLA submission is complete. The result of the FDA's review is either a filing letter or, in rare instances, an RTF.

59. If the BLA submission is acceptable for review, the PDUFA indicates that the FDA intends to review 90% of standard BLA submissions within ten months of the sixty day filing date and 90% of priority BLA submissions within six months of the sixty day filing date. The date at the end of the review period is generally referred to as the PDUFA date.

60. In sum, in order to obtain a biologics license for leronlimab, CytoDyn needed to adhere to the foregoing process and timely submit a BLA containing the necessary information to the FDA.

2. The FDA's Use of Emergency Use Authorizations (EUA) in Lieu of The BLA Process

61. In extraordinary circumstances, biotechnology or drug companies can seek to distribute a drug under a rarely used process called Emergency Use Authorization ("EUA"). Under Section 564 of the FD&C Act, when the Secretary of the United States Department of Health & Human Services ("HHS") declares that an emergency use authorization is appropriate, the FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or other threats when certain criteria are met, including where there are no adequate, approved, and available alternatives.

62. According to the FDA, the EUA "authority allows FDA to help strengthen the nation's public health protections . . . infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies." In the recent past, the FDA issued EUAs for Anthrax Vaccine Adsorbed, H1N1 (i.e., swine flu), Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Ebola virus, and Zika Virus.

63. On January 31, 2020, the Secretary of HHS issued a Determination that a Public Health Emergency Exists and declared: "As a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV), . . . a public health emergency exists and has existed since January 27, 2020, nationwide." On February 4, 2020, the Secretary of HHS issued another determination that "Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act." And on March 27, 2020, with an effective date of February 4, 2020, the Secretary of the HHS declared that the FDA Commissioner could issue EUA for drugs and biological products for emergency use under section 564 of the FD&C Act."

64. The FDA recommends that an EUA request contain safety and efficacy data for a product, among other categories of information. While clinical trials are not required for an EUA submission, they are recommended for otherwise unapproved products, such as leronlimab. Further, the FDA "encourages any [applicant] of a candidate product to have early discussions with FDA . . . about the nature and type of safety data that might be appropriate."

3. "Emergency" and Expanded Access/Compassionate Use

65. The FDA's "emergency use" exemption allows the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and there is not sufficient time to obtain Institutional Review Board ("IRB") approval.

66. Separately, according to the FDA, expanded access, sometimes called "compassionate use," involves the use of an investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options.

67. This mechanism is primarily intended to give seriously ill patients access to experimental drugs or devices where no comparable or satisfactory alternative treatment is available. Although the test article applicant is expected to continue conventional clinical trials and pursue marketing approvals with due diligence, expanded access studies involve systematic use of experimental treatments, and, with very rare exceptions, require rigorous review and approval, including both IRB approval and FDA approval in the form of an IND (drug/biologic).

C. CytoDyn Pins Its Hopes for a Marketable Product on Leronlimab

68. Leading up to and during the Class Period, CytoDyn's financial success, e.g., earning *any* revenue, let alone profits, hinged on the Company's ability to obtain regulatory approval to market and sell leronlimab.

69. Indeed, leading up to and during the Class Period, CytoDyn articulated various "Risks Related to Our Business." For example, in risk disclosures published on August 14, 2019, CytoDyn stated:

> We have not generated any revenue from product sales, licensing, or other potential sales to date. Since our inception, we have incurred operating losses in each year due to costs incurred in connection with research and development activities and general and administrative expenses associated with our operations. Our current drug candidate, leronlimab, is in the later stages of clinical trials and the filing of a BLA is underway. During the fiscal years ended May 31, 2019 and 2018, we incurred net losses of approximately $56.2 million and $50.1 million, respectively, and at May 31, 2019, we had an accumulated deficit of approximately $229.4 million and a stockholders' deficit of $8.9 million. We expect to incur losses for the foreseeable future as we continue development of, and seek regulatory approvals for, our drug candidate and commercialize any approved product usages. If our current drug candidate fails to gain regulatory approval, or if it or other candidates we own do not achieve approval and market acceptance, we will not be able to generate any revenue, or explore other opportunities to enhance stockholder value, such as through a sale. If we fail to generate revenue and eventually become and remain profitable, or if we are unable to fund our continuing losses, our shareholders could lose all or part of their investments.

70. Absent any revenues from its business, in the years leading up to and during the Class Period, CytoDyn had been constrained to fund its operations through various alternative financing arrangements with less than reputable partners.

D. CytoDyn's Financial Circumstances Leading up to the Class Period

1. CytoDyn Has Never Generated Any Revenue

71. CytoDyn has never generated any revenue, but has incurred operating losses each fiscal year due to costs of research and development activities and general administrative expenses. From 2019 to 2020, CytoDyn's losses essentially doubled, from $56.2 million in 2019 to $124.4 million in 2020. Since 2012, CytoDyn's annual net losses were as follows:

FY	Net Losses
2012	$7,474,224
2013	$9,568,301
2014	$12,431,413
2015	$25,088,070
2016	$25,703,612
2017	$25,763,801
2018	$50,149,681
2019	$56,186,660
2020	$124,403,402

72. CytoDyn's accumulated deficit also jumped from $229.4 million in 2019 to $354.7 million in 2020. In 2020, CytoDyn's financial health was so dire that in connection with its audit of CytoDyn's financial statements for FY20, CytoDyn's auditor issued a "going concern" warning regarding CytoDyn's ability to continue as a business:

> Our auditors issued an opinion, which includes a going concern exception, in connection with the audit of our annual financial statements for the fiscal year ended May 31, 2020. A going concern exception to an audit opinion means that there is substantial doubt that we can continue as an ongoing business for the next 12 months. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third-parties. There is no assurance that we will be able to adequately fund our operations in the future.

2. CytoDyn Struggles to Obtain Alternative Financing Resources to Fund Its Operations

73. With no revenues, CytoDyn relied on funding from institutional investors in order to operate. However, the Company's leadership, in particular Pourhassan, repeatedly created complications and impediments to funding. Basic background research on Pourhassan indicates two filings for Chapter 7 Bankruptcy (in 2001 and 1991) as well as multiple criminal charges and/or convictions, between 1986 and 2006. Moreover, Pourhassan had no apparent training, experience or background in the medical or pharmaceutical field, prior to joining CytoDyn.

74. Pourhassan's role as CytoDyn's CEO has prevented the Company from obtaining funding from institutional investors. In April 2018, Goldman Sachs Partners Fund informed CytoDyn that it would not do business with CytoDyn unless Pourhassan was replaced. In November 2018, Ziff Capital Partners and Bain Capital were prepared to invest $30 million each, but chose not to do so because of Pourhassan.

75. Further, in December 2018/January 2019, Jason Silvers ("Silvers") of Goldman, Sachs & Co.'s Health Care and M&A Groups indicated that he was willing to work to help CytoDyn raise capital from institutional investors, but during the course of discussions, it became clear that Silvers did not want to work with Pourhassan.

76. On May 8, 2019, five members of the Board, including Pourhassan, met with Steven Altschuler ("Altschuler") of Ziff Capital Partners. Altschuler purportedly made clear that CytoDyn would need to replace Pourhassan as CEO for him to consider working with CytoDyn.

77. In order to obtain the funding CytoDyn needed to survive *and* remain CEO, Pourhassan turned to John Fife ("Fife") and his so-called "vulture fund[s]."[4] In 2007, the SEC charged Fife with violations of 10(b) of the Exchange Act and Rule 10b-5 thereunder for his participation in an annuity market timing scheme. *SEC v. Fife, et al.*, No. 07-cv-0347 (N.D. Ill. Jan. 18, 2007). That case settled after Fife consented to an injunction, monetary relief, and a bar from associating with an investment adviser, with the right to reapply after eighteen months. In 2012, the Financial Industry Regulatory Authority ("FINRA") barred Fife from association with any FINRA member for failing to respond to FINRA requests for information. FINRA Case No. 2011029203701 (March 2012).

78. On June 26, 2018, CytoDyn entered into the first of four Securities Purchase Agreements with a Fife-owned fund, Iliad Research and Trading, L.P. ("Iliad"), whereby CytoDyn issued a convertible promissory note in the initial principal amount of $5.7 million. Iliad gave consideration of $5.0 million. As part of the agreement, Iliad had the option to convert all or part of the outstanding balance into shares of common stock at an initial conversion price of $0.55 per share.

79. CytoDyn entered into a second Securities Purchase Agreement with Iliad on January 30, 2019, whereby CytoDyn issued a convertible promissory note in the initial principal amount of $5.7 million. Iliad gave consideration of $5.0 million. As part of the agreement, Iliad had the option to convert all or part of the outstanding balance into shares of common stock at an initial conversion price of $0.50 per share.

[4] According to the NASDAQ online glossary, a vulture fund is "[a] fund that buys distressed debt of commercial companies or sovereign nations at a cheap price and then often sues them for the entire value of the debt. The resemblance to vultures is because these funds profit from the debt of failing companies or poor nations."

80. Thereafter, on March 31, 2020, CytoDyn entered into a third Securities Purchase Agreement with Iliad, whereby CytoDyn issued a convertible promissory note in the initial principal amount of $17.1 million. Iliad gave consideration of $15.0 million. As part of the agreement, Iliad had the option to convert all or part of the outstanding balance into shares of common stock at an initial conversion price of $4.50 per share. However, the conversion price of the promissory note was made subject to full-ratchet anti-dilution protection, pursuant to which the conversion price would be automatically reduced to equal the effective price per share in any new offering by CytoDyn of equity securities.

81. Three months later, on July 29, 2020, CytoDyn entered into a fourth Securities Purchase Agreement with Iliad, whereby CytoDyn issued a convertible promissory note in the initial principal amount of $28.5 million. Iliad gave consideration of $25.0 million. As part of the agreement, Iliad had the option to convert all or part of the outstanding balance into shares of common stock at an initial conversion price of $10.00 per share.

82. Then, on September 3, 2020, the SEC filed a lawsuit against Iliad, Fife and certain other Fife-related entities. In a Litigation Release titled, "SEC Charges Unregistered Penny Stock Dealer," the SEC described its complaint against Iliad and related entities as follows:

> [B]etween 2015 and 2020, Fife, and his companies, Chicago Venture Partners, L.P., Iliad Research and Trading, L.P., St. George Investments LLC, Tonaquint, Inc., and Typenex Co-Investment, LLC, regularly engaged in the business of purchasing convertible notes from penny stock issuers, converting those notes into shares of stock at a large discount from the market price, and selling the newly issued shares into the market at a significant profit. The SEC alleges that Fife and his companies engaged in more than 250 convertible transactions with approximately 135 issuers, sold more than 21 billion newly-issued penny stock shares into the market, and obtained more than $61 million in profits. The complaint also alleges that, at the time of the conduct, the Defendants were not registered with the SEC as dealers, in violation of the mandatory registration provisions of the federal securities laws. It further alleges that by failing to register, the Defendants avoided certain regulatory obligations for dealers that govern their conduct in the marketplace, including regulatory inspections and oversight, financial reporting requirements, and maintaining books and records.

Litigation Release No. 24886; *SEC v. Fife, et al*., No. 20-cv-05227 (N.D. Ill. Sept. 3, 2020).

83. Two months later, on November 11, 2020, CytoDyn announced in a press release that it had "completed an additional non-dilutive convertible debt offering" with an unnamed "institutional investor." Similar to prior deals, the institutional investor secured a promissory note for $28.5 million in exchange for consideration of $25 million. CytoDyn did not disclose the identity of the "institutional investor" in the November 11, 2020 press release. Investors later learned that the "institutional investor" referred to in the November 11, 2020 press release was another Fife-related entity, Streeterville Capital LLC, which the SEC had *not* named in its complaint against Iliad and Fife. Streeterville Capital LLC had registered in Utah on September 9, 2020, six days after the 2020 SEC complaint was filed.

84. Thereafter, CytoDyn completed two more convertible debt offerings with Streeterville Capital, LLC for a total of $50 million in proceeds to the Company. On April 23, 2021, CytoDyn entered into eighth convertible debt offering with another Fife-related entity, Uptown Capital, LLC, for an additional $25 million in proceeds.

85. Overall, from mid-2018 through April 23, 2021, CytoDyn issued $142.5 million in convertible notes to Fife-related entities, and received $125 million in cash. Critically, however, CytoDyn's "recent convertible note financings" including some of those described above, "require[d] [the Company] to make debt repayments of $7.5 million per month to retire earlier incurred debt." According to the Company's FY21 Form 10-K, CytoDyn was "required to use a significant portion of [its] available cash to make these debt repayments" or, more importantly for shareholders, negotiate with Fife to "exchange all or part of [the] outstanding debt for shares of common stock. . . . at a discount to the market price" leading to "additional dilution to [CytoDyn's] existing shareholders." CytoDyn therefore warned investors that "the issuance of additional equity or convertible debt securities could have an adverse effect on the market price of our common stock."

E. CytoDyn Needs to Convince Investors it Can Gain Regulatory Approval to Market Leronlimab

1. Leading up to the Class Period, CytoDyn Represents That Leronlimab May Have Various Indications, but Focuses on HIV

86. CytoDyn's long-term ability to survive turned on obtaining regulatory approval to market and sell leronlimab. Investors had no other reason to invest money in the Company. In the years and months leading into the Class Period, Defendants had represented that the Company's efforts to achieve such approval for a BLA for an HIV indication ("HIV BLA") were making substantial progress. On July 16, 2018, CytoDyn announced the results for its pivotal Phase 3 trial studying the use of leronlimab in a combination therapy to treat HIV.

87. In March 2019, Pourhassan told the *Portland Business Journal* that CytoDyn "would file the full [BLA] application by the end of 2019 and would have revenue in 2020." During a May 3, 2019 investor presentation regarding leronlimab, CytoDyn shared slides showing a litany of "Important Milestones" for HIV in 2019: [leronlimab]

PRO 140 Important Milestones for HIV and Cancer 2019

CytoDyn

Milestones	Target Dates
BLA submission – HIV combination therapy – unmet medical need	3Q2019
Revenue potential of about $480 million	2020
Initiate first ever monotherapy Phase 3 pivotal trial	1H2019
Triple-Negative Breast Cancer study first patient injected	2Q2019
Triple-Negative Breast Cancer study interim results	2019
GvHD interim results	2H2019
Prognostic test licensed – 510(k) filing with the FDA	1H2019
IND-Protocol for colon cancer Phase 2	1H2019
Large Pharma discussion for potential licensing or partnering	1H2019
8 preclinical studies with leronlimab - Filing 8 INDs for 8 Phase 2 trials (if results of preclinical studies are positive)	2019

Ticker Symbol: CYDY 19 www.cytodyn.com

88. In a June 13, 2019 press release Pourhassan stated, "[t]he results of this pivotal trial [i.e., the Phase 3 combination therapy trial] is the basis for our current BLA filing" and "we expect to submit the remaining two parts of our BLA filing for rolling review with the U.S. Food and Drug Administration by the third quarter of 2019 and remain actively engaged in potential strategic discussions related to leronlimab." However, CytoDyn soon pushed back the deadline and represented, on June 17, 2019, in a press release, "CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in 2019 for that indication."

89. On August 5, 2019, CytoDyn signaled further progress on the HIV BLA submission, as well as traction with the FDA, when it stated in a press release that it was granted "a small business waiver of application fees by" the FDA for the forthcoming HIV BLA. Defendants also reiterated in an October 11, 2019 press release that the FDA already had agreed to provide CytoDyn with a "Fast Track" designation for the HIV BLA, such that the submission would receive prompt attention from the FDA.

90. Further signaling an imminent HIV BLA submission, in a press release dated November 21, 2019, CytoDyn stated that it had "successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in 2019 for that indication."

91. Defendants had in fact been meeting with the FDA about the contemplated HIV BLA. In particular, on December 16, 2019, in a non-public communication to the Company, the FDA communicated specific data and information that CytoDyn needed to include in the leronlimab BLA, stating:

> We acknowledge that you have selected 700 mg as the to be marketed dose. Assessing whether the data from CD03 and CD02 support the 700 mg dose for the intended population and indication will be a review issue. With 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 pharmacokinectics and exposure-response relationship analyses), receptior 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). The integrated assessment should reflect data from the 3 doses evaluated in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02.

92. CytoDyn did not share this communication or guidance, nor other specific guidance it had previously received from the FDA, with the public at any time before or during the Class Period. This information did not become public until October 26, 2021, when, in the context of litigation between Amarex (the CRO used by CytoDyn to manage various aspects of the HIV BLA)[5] and CytoDyn, the foregoing language was disclosed. *CytoDyn, Inc. v. Amarex Clinical Research, LLC, et al*., No. 21-cv-02533 (D. Md. Oct. 4, 2021).

93. However, again signaling strong progress toward the complete submission of the HIV BLA, on December 17, 2019, CytoDyn issued a press release stating that it had "entered into a Commercialization and License Agreement (CLA) and a related Supply Agreement to commercialize leronlimab (PRO 140) in the U.S. for the treatment of HIV [with Vyera Pharmaceuticals, LLC]" and:

> Under the terms of the CLA, CytoDyn will maintain responsibility for the development and FDA approval of leronlimab for all HIV-related and other indications, while Vyera has been granted an exclusive license to market and distribute leronlimab in the U.S. for the treatment of HIV. In exchange for such exclusive license, Vyera has agreed to pay upfront and regulatory and sales-based milestone payments of up to $87.5 million, as well as a royalty of 50 percent on net sales. Vyera also agreed to make an investment in CytoDyn of $4 million in the form of registered CytoDyn common stock.

[5] In particular, Amarex is a clinical research organization ("CRO") that engages in the business of providing clinical trial management services and consulting. In May 2014, Amarex agreed to provide CytoDyn with certain clinical trial management services regarding leronlimab. At all relevant times, Amarex's CEO was Kazempour and its Senior Vice President of Clinical Operations was Kush Dhody ("Dhody").

94. Vyera Pharmaceuticals, LLC's ("Vyera") (formerly Turing Pharmaceuticals, LLC) founder was Martin Shkreli, who was widely criticized when in late 2015 when Turing obtained the manufacturing license for the antiparasitic drug Daraprim and raised its price by a factor of 56 (from $17.50 to $750 per pill) and was later charged and convicted in federal court on two counts of securities fraud and one count of conspiring to commit securities fraud.

95. On January 13, 2020, after missing its stated goal to file the HIV BLA in 2019, CytoDyn issued a press release that stated, "CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a [BLA] in the first quarter of 2020 for that indication." CytoDyn issued identical statements in subsequent press releases from January through March 2020.

96. In a Form 8-K filed on January 21, 2020, CytoDyn announced seeming progress, stating, "CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a [BLA] in the first quarter of 2020 for that indication."

97. At the end of the first quarter of 2020, however, CytoDyn pushed the submission target date again. On March 30, 2020, CytoDyn stated in a press release that "CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a [HIV BLA] in April of 2020 for that indication." CytoDyn issued identical statements in ten subsequent press releases over the following three weeks.

98. CytoDyn's prospects rode on its ability to successfully submit the BLA that it had been trumpeting for nearly a year. And yet, after months of anticipatory public statements, it still had failed to take the critical next step and submit the BLA application package to the FDA. The stalled, crucial process weighed on the Company, and on the minds of investors and Defendants.

2. Disregarding the FDA's Specific Instructions, CytoDyn Finally Submits BLA Despite Knowledge That It Lacks Required Data and Information

99. Pourhassan, pressured to show successful progress, was unable to wait for the BLA submission any longer. In an e-mail to the BLA project heads, he demanded that the application be submitted ***regardless*** of the internally well-known gaps and data deficiencies it contained. On April 14, 2020, Pourhassan sent an e-mail to Dhody, Kazempour, and Nitya Ray, CytoDyn's Chief Technology Officer:

> Dear Nitya and Kush:
>
> Today we have so far in 1 hour almost 20% drop in our stock price. Yesterday we had drop also after putting out great results about COVID-19 patients we are seeing these 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.***
>
> Dear Nitya: Please communicate with Kush about how much time they need to prepare the CMC[6] portion after you send it to them. Kush told me yesterday he needs one week if so, they need the CMC package tomorrow to make the next week's Wednesday deadline. Please talk to Kush to see if there is any way they could take 1-2 days to prepare the CMC portion for final filling as you and I discussed yesterday
>
> Dear Kush: The COVID-19 is no longer CytoDyn's top priority as if the stock continues its drift then financially we will have problems financing itself. ***THE MOST IMPORTANT thing now is BLA. Please focus on that urgently only***.

[6] "CMC" refers to the "Chemistry Section: (A) Chemistry, manufacturing, and controls information (*e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2*)" requested in connection with a BLA.

100. An image of Pourhassan's April 14, 2020 e-mail is below:

From: Nader Pourhassan <npourhassan@cytodyn.com>
Sent: Tuesday, April 14, 2020 10:49 AM
To: Kush Dhody <kushd@amarexcro.com>; Kazem Kazempour <kazemk@amarexcro.com>
Cc: Nitya Ray <nray@cytodyn.com>
Subject: BLA submission

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Nitya and Kush:
Today we have so far in 1 hour almost 20% drop in our stock price. Yesterday we had drop also after putting out great results about COVID-19 patients we are seeing these 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.

Dear Nitya: Please communicate with Kush about how much time they need to prepare the CMC portion after you send it to them. Kush told me yesterday he needs one week if so, they need the CMC package tomorrow to make the next week's Wednesday deadline. Please talk to Kush to see if there is any way they could take 1-2 days to prepare the CMC portion for final filling as you and I discussed yesterday

Dear Kush: The COVID-19 is no longer CytoDyn's top priority as if the stock continues its drift then financially we will have problems financing itself. THE MOST IMPORTANT thing now is BLA. Please focus on that urgently only.

With best regards
Nader

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101. Pourhassan's April 14, 2020 e-mail did not become public until October 26, 2021, when Amarex filed it as an exhibit to Kazempour's sworn declaration in its litigation against CytoDyn. Importantly, Kazempour also stated under oath in his declaration that Pourhassan had been "warned" about the deficiencies in the HIV BLA.

102. Despite a litany of deficiencies in the submission package about which Defendants knew but did not disclose to investors, CytoDyn submitted the HIV BLA to the FDA in late April 2020.

103. On April 27, 2020, through a press release titled, "CytoDyn Submits ***Completed*** Biologics License Application (BLA) to the FDA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients," Pourhassan stated:

> With the BLA filing for a combination therapy now complete, we are continuing our efforts on commercialization-readiness, as well as advancing leronlimab in the other important therapeutic areas of COVID-19, cancer and immunology. ***The BLA filing is a monumental achievement for our Company*** . . . .

104. Also on April 27, 2020, during a conference call with investors, Pourhassan explained away the delay in the HIV BLA submission and stated:

> [H]ave some exciting news for the use of leronlimab in treating patients infected with COVID-19 . . . .
>
> ***
>
> The first update is the BLA submission, which is a historical achievement for CytoDyn.
>
> As everyone knows, the BLA timeline was pushed back constantly. These push-backs were all due to CytoDyn's success. The first success is with a higher dose of leronlimab in monotherapy. Then it got pushed back because of the success of leronlimab application in coronavirus and overwhelming interest from hospitals and patients to get leronlimab, which led to initiation of two new clinical trials, which takes a tremendous amount of work from our CRO and our CytoDyn team.
>
> Then it got pushed back because of the coronavirus shutdown of the lab side, and even the manufacturing of leronlimab that shorted [out] the availability of our stability data from AGC.
>
> ***
>
> Our success with cancer also contributed to our delay of the BLA.

> ***
>
> The good news is, CytoDyn just filed the full BLA last night without slowing down our cancer programs, without slowing down our impressive work in coronavirus, and without blinking on the tremendous financial pressure from everywhere.
>
> ***
>
> Congratulations to Am[a]rex for not letting down all of our shareholders and many patients in great need of leronlimab. Special thanks goes to Dr. [Kush Dhody] and the main person at Am[a]rex, their CEO, Dr. [Kazem Kazempour], and to CytoDyn's team, especially our Chief Technology Officer, Dr. Nitya Ray who took the CMC shattered pieces and successfully put it back together in an artistic fashion; and in doing so, he also finalized a superb deal for CytoDyn with Samsung Biologics. ***So in short, ladies and gentlemen, the BLA is submitted***.
>
> ***
>
> It is very important, as CytoDyn's story gets unfolded, that shareholders realize the value that one man has brought to us, and he is CytoDyn's chairman of the board and chief medical officer, Dr. Scott Kelly. . . . As the CEO of CytoDyn, I went through a lot of challenges in the last eight years, and without Dr. Kelly, most of our victories would not been [sic] possible. . . . ***The BLA got filed***.

(Second set of brackets in original.)

105. On April 28, 2020, H.C. Wainwright & Co., an analyst covering CytoDyn, accepted Defendants' disclosure, and on the strength of the news, increased the Company's valuation by ***$700 million*** and its target price per share to $4.00. In particular, the analyst reported that, "[y]esterday, CytoDyn announced that it had submitted the clinical and the chemistry, manufacturing and controls (CMC) portions of the Biologics License Application (BLA) to the FDA for leronlimab as a combination therapy with highly active antiretroviral therapy (HAART) for highly treatments experienced HIV patients." Further, the analyst stated, "[t]he FDA has granted Fast Track designation and rolling review of the leronlimab BLA. Therefore, we believe that the FDA should complete the review process within six months and potentially grant regulatory in 2H20." Additionally:

> In the wake of this derisking event and in light of leronlimab's newly-discovered effectiveness in treating COVID-19, we have decided to lower the discount rate to 12% from 15% and to increase the probability of approval in COVID-19 to 50% from 35%. Our estimated market value of the firm has increased to $2.4B from

> $1.7B. Using 600M fully diluted shares, this leads to a value of approximately $4 per share. Therefore, we reiterate our Buy rating while raising the 12-month price target to $4 from $3 per share.

106. In the coming days, Defendants reiterated repeatedly that the HIV BLA application had been "completed" and submitted to the FDA. For example, on April 30, 2020, in a press release, CytoDyn again affirmed, "CytoDyn completed the filing of its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients."

107. On May 4, 2020, buried deep within a press release regarding the Company's request for compassionate use clearance for leronlimab to treat COVID-19, CytoDyn stated, "[w]e would like to provide an update that the Biologics License Application (BLA) for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients will be considered completed after the clinical datasets are submitted on May 11, 2020." This was the first disclosure to incrementally inform the market of shortcomings with the HIV BLA submission. CytoDyn's stock price dropped approximately 13% on the news on May 4, 2020, on significant trading volume.

108. On May 6, 2020 and again on May 7, 2020, CytoDyn issued press releases echoing the same information, and on May 8, 2020, CytoDyn issued a press release that stated, "[t]he 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."

109. On May 13, 2020, H.C. Wainwright & Co., an analyst covering CytoDyn, reported that "CytoDyn has confirmed that on May 11, 2020, it submitted all remaining parts of the Biologics License Application (BLA) for leronlimab as a combination therapy with highly active anti-retroviral therapy (HAART) for highly treatment-experienced HIV patients to the

FDA." On news of the completion of this step, the firm reiterated its valuation for CytoDyn: "We reiterate our Buy rating and 12-month price target of $4 per share."

110. On May 15, 2020, CytoDyn issued a press release and stated, "[t]he Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients with the FDA on April 27, 2020, and submitted additional FDA requested clinical datasets on May 11, 2020."

111. Therafter, Defendants extolled the purported progress of the application and positive feedback the Company had received from the FDA. For example, during a June 5, 2020, Proactive Investors interview, Pourhassan stated, that CytoDyn was communicating with the FDA regarding the BLA and "had the discussion with the [FDA] just a few days ago, very, very positive discussions."

3. The FDA Swiftly Rejects Defendants' Gap-Ridden HIV BLA Submission in a Non-Public RTF Letter

112. On July 8, 2020, however, Defendants' fraud hit a wall. That day, the FDA informed CytoDyn in a non-public communication that it had rejected CytoDyn's HIV BLA submission after just a preliminary review, and provided CytoDyn with a "Refuse to File" notification:

> After a preliminary review, we find your application does not contain all pertinent information and data needed to complete a substantive review. Therefore, we are refusing to file this application under 21 CFR 601.2(a).
>
> The application 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.
>
> We are refusing to file this application for the reasons identified below. Section I provides a high-level summary of the deficiencies and Section II provides a detailed description of each deficiency and the information needed to resolve the deficiency.

113. The substance of the FDA's RTF Letter was not disclosed to the public at that time. Indeed, the full substance of the RTF Letter was not made public until October 26, 2021, in the litigation between Amarex and CytoDyn.

114. The FDA, through the RTF Letter, provided a veritable laundry list of basic, critical information and data that Defendants had failed to include in the HIV BLA filed in April 2020.

115. Much of the missing data, the FDA reminded Defendants, was information that the agency had specifically told Defendants must be included in the HIV BLA during pre-BLA communications. Among other points, the FDA stated:

> The BLA does not include critical information and analyses needed to permit substantive clinical, statistical, clinical virology and clinical pharmacology review of your proposed dose. In many cases, these issues are deficiencies that were clearly communicated to you before submission of the application (see Section II for specific details). These deficiencies require resolution before a meaningful review can occur.

116. The FDA also stated:

> There is an absence of important variables (e.g., time to virologic failure at the assigned dose) and analysis group flags in the analysis files containing the primary efficacy data needed for substantive clinical, statistical, clinical virology and clinical pharmacology review of your product. Additionally, the datasets have numerous instances of missing data and the files are not adequately defined or properly indexed.

117. The FDA further noted:

> Assessing the safety and effectiveness in subpopulations (sex, age, race, and ethnicity) is an integral part of the BLA review. Your BLA did not include analyses of subpopulations with regard to effectiveness; the Summary of Clinical Efficacy, the CD02 CSR, and the CD03 CSR did not include these analyses and the ISE was omitted from the submission. While the ISS and Summary of Clinical Safety included sections with relevant titles such as "Adverse Events by Age" and "Adverse Events by Gender", the content of these sections was largely line-listings without substantive assessments addressing whether age or sex appeared to have impacted safety outcomes in your clinical development program. Neither the ISS nor the Summary of Clinical Safety includes analyses of safety by race or ethnicity.

118. Showing the extent of the deficiencies in the application (which Pourhassan had demanded be filed despite its glaring holes), the FDA also noted that "[n]o data from studies conducted with the drug in the device were included in the submission, and no information is included on the manufacturer of the syringe and needles."

119. The FDA further explained in the RTF letter that, on December 16, 2019, it had expressly told CytoDyn:

> We acknowledge that you have selected 700 mg as the to be marketed dose. Assessing whether the data from CD03 and CD02 support the 700 mg dose for the intended population and indication will be a review issue. With 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 pharmacokinectics and exposure-response relationship analyses), receptior 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). The integrated assessment should reflect data from the 3 doses evaluated in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02.

120. Reminding CytoDyn that it *already* articulated the data that should be submitted with the BLA (on prior two occasions), the FDA stated:

> Despite the specific advice above, which echoed the advice we provided you on January 22, 2019, following our presentation of the revised BLA submission plan to the CDER's Medical Policy and Program Review Council (MPPRC), the BLA includes only a 2-page "Rationale for Dose Section" that is identical to the rationale you provided with the proposed CD08 trial, which we told you in our June 3, 2019, correspondence was insufficient.
>
> Your application does not include the information and analyses needed to permit FDA reviewers (clinical, statistical, clinical virology and clinical pharmacology) to perform a substantive review of the proposed dose. The application is missing an integrated assessment that incorporates detailed summaries reflecting data from the participants randomized to receive 350 mg, 525mg, and 700mg in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02. Furthermore, your application does not include multiple reports that are needed to permit a substantive review.

121. The FDA also provided detailed descriptions, across a further 18.5 pages, regarding the deficiencies in CytoDyn's BLA.

122. Notably, RTFs are exceedingly rare—industry observers estimate between January 1, 2008 and December 31, 2017, only 4% of the new applications and efficacy supplements received a RTF.

4. CytoDyn Seeks to Explain Away and Misrepresent the True Substance of the RTF

123. On July 13, 2020, CytoDyn shocked the market when it disclosed that it had received the RTF Letter from the FDA for the HIV BLA. Defendants did not admit that CytoDyn had submitted (and resubmitted) the HIV BLA despite knowing that it lacked critical information, including various data the FDA had explicitly told CytoDyn the BLA must contain in order to be deemed complete. Nor did Defendants admit that they had knowingly submitted (and resubmitted) the application with grossly inadequate supporting data on Pourhassan's express orders. Nevertheless, the market understood that CytoDyn's BLA had been so facially deficient as to warrant immediate rejection by the FDA—and critically, from a valuation perspective, that any regulatory approval for the purported HIV indication for leronlimab would be delayed ***indefinitely***.

124. On this news, on July 13, 2020, the price of CytoDyn's common stock fell by $1.03 per share—nearly 22%—from a close of $4.73 on July 10, 2020 to a close at $3.70 on July 13, 2020, on abnormally high trading volume of 21,148,900 shares.

125. On and after July 13, 2020, CytoDyn scrambled to perform damage control, and assure investors that the issues the FDA had identified with the rejected BLA were not significant, and the application could be salvaged. Defendants also pivoted hard, and increasingly referenced a fallback plan for leronlimab—approval as a treatment for COVID-19.

126. For example, during a July 13, 2020 CytoDyn Conference Call, Pourhassan stated that the purpose of "[t]oday's call is to explain the letter from the FDA requesting information about our BLA filing that has received a Refuse-to-File and did not get the PDUFA date." Pourhassan stated:

> In 2018, CytoDyn announced that the company had hit its primary endpoint in the HIV indication for the MDR population — multi drug-resistant population.
>
> ***
>
> In 2019, CytoDyn met with the FDA on a pre-BLA meeting, and was able to receive a rolling review for its BLA submission. FDA also requested the BLA submission should be for a higher dose of 700 milligrams, since the company had shown success with a 700 milligram dose as compared to a 350 milligram dose.
>
> ***
>
> The FDA requested CytoDyn to enroll at least fifty patients and obtain data at 24 weeks with the 700 milligram dose in CD03, which is our monotherapy trial to demonstrate safety of the 700 milligram dose. CytoDyn achieved this in October 2019, and the BLA included information about CD03 trial for the safety portion of the BLA.
>
> ***
>
> ***CytoDyn felt the application was completed for the FDA to provide the PDUFA date.***

127. In offering excuses, however, Defendants left out critical facts about the myriad data the HIV BLA was missing, the fact that the FDA had expressly called for many of these data in pre-application communications with CytoDyn, and the fact that Pourhassan had directed his team to file the BLA regardless of known holes.

128. Defendants sought to hide the substance of the FDA's RTF Letter from the public, even when asked to explain it. Specifically, during the July 13, 2020 conference call noted above, analyst Robert Smith asked "[i]n the interest of being clear and transparent, why not just share the FDA letter with us, with the shareholders?" Pourhassan responded: "[L]et me answer the first question. Sharing the FDA letter with a forth [sic] public. No company that I know give [sic] to their shareholders—the FDA's communication to the public."

129. In the nearly one and a half years since this corrective event, in which Defendants revealed the FDA had rejected their materially incomplete HIV BLA submission, they have relentlessly spun the fiasco as nearly corrected.

130. For example, on January 29, 2021, CytoDyn issued a press release, stating that it had "been working diligently to refile its [BLA] for this HIV combination therapy since receiving a Refusal to File in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the filing. CytoDyn expects to refile its BLA in the first half of calendar year 2021." CytoDyn expressed the same message through eight subsequent press releases between February and April, 2021.

131. On February 18, 2021, the SEC sent CytoDyn's CFO, Defendant Mulholland, a letter regarding the Company's Form 10-K for the Fiscal Year ended May 31, 2020. In the letter, which was posted to the EDGAR website, the SEC issued targeted inquiries concerning CytoDyn's BLA, specifically: (i) the timeline of CytoDyn's communications with the FDA prior to submitting the BLA; (ii) how the RTF impacted CytoDyn's timing in respect to efforts to capitalize inventory with respect to leronlimab; (iii) the nature of additional information required by the FDA in order to resubmit the BLA; and (iv) "why your projected date for resubmitting the BLA keeps slipping."

132. After reviewing CytoDyn's March 23, 2021 response, on April 16, 2021, the SEC issued another letter to Mulholland. In the letter, which was posted to the EDGAR website, the SEC asserted that certain responses of CytoDyn failed to sufficiently respond to the SEC's inquiries, including responses "to support management's assertion that prelaunch inventory represented an asset at each date it was capitalized" and questioned the appropriateness of CytoDyn's capitalization conclusions. Specifically:

- You assert that your meetings with the FDA addressed safety and efficacy of the drug. However, the FDA's July 2020 Refusal to File letter states that your Biologics License Application omitted information necessary for the FDA to perform a substantive review of the product's safety and effectiveness.
- You indicate that "…current scientific work being performed by the Company to complete a successful resubmission of the Company's BLA" is ongoing and that you do not expect to resubmit your BLA until mid-calendar year 2021 or shortly thereafter.
- You assert that you manufactured leronlimab consistent with cGMP

> standards. However, we note that the FDA's September 20, 2020, response to your list of questions related to the Refusal to File letter continued to reference issues with your clinical and statistical data, device related issues, and chemical manufacturing and control related issues.

(Alteration in original.)

133. After reviewing CytoDyn's May 7, 2021 response, on May 19, 2021, the SEC sent Mulholland another letter. In the letter, which was posted to the EDGAR website, the SEC asked CytoDyn to respond to follow-up questions regarding the BLA and also to "[e]nsure you also discuss and update the risks and uncertainties surrounding market acceptance and salability of leronlimab in your future periodic reports."

134. During the Company's exchange with the SEC, on May 5, 2021, CytoDyn further pushed out the potential HIV BLA submission date, stating that it had purportedly "been working diligently to resubmit its [BLA] for this HIV combination therapy since receiving a Refusal to File letter in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the submission. ***CytoDyn expects to resubmit its BLA via a rolling submission starting in the third quarter of calendar 2021***." CytoDyn expressed the same message through subsequent press releases.

135. However, as recently as December 1, 2021 CytoDyn has not submitted a complete HIV BLA to the FDA.

F. Knowing That the HIV BLA is All but Doomed to Fail as Facially Inadequate, CytoDyn Opportunistically Shifts Focus to COVID-19

136. Prior to January 2020, CytoDyn was a struggling microcap biotech company with a penny stock trading OTC at well under $1.00 per share. For seven years, Defendants unsuccessfully sought FDA approval for the market and sell leronlimab to treat HIV patients. As explained above, CytoDyn's HIV BLA had already been delayed months—if not years, due to Defendants' flagrant and knowing disregard for FDA filing requirements. At the start of the

Class Period, Defendants were no closer to FDA approval for HIV, cancer or, indeed, ***any*** indication for leronlimab (and, to date, Defendants still have not obtained such approval).

137. Out of time, money, and excuses, the COVID-19 pandemic presented Defendants with a golden opportunity to commit a fraudulent stock promotion scheme that increased the price of CytoDyn's common shares by 900%, allowing the Individual Defendants to sell tens of millions of CytoDyn shares at historically high prices and CytoDyn to stay afloat through the issuance of convertible debt and the exercise of previously issued warrants. As explained herein, Defendants violated Section 10(b) and Rule 10b-5(a & c) by engaging in this stock promotion scheme. Defendants' Class Period statements and promotional efforts (including paying tens of thousands of dollars to promotional websites and services) presented the façade that: (i) leronlimab was safe and effective for the treatment of COVID-19; (ii) the results of Phase 2 (CD10) and Phase 2b/3 (CD12) Trials (defined herein) demonstrated that leronlimab was effective in treating COVID-19; (iii) U.S., U.K., and Canadian (among others) regulatory authorization to market and sell leronlimab to treat COVID-19 was imminent; and (iv) CytoDyn would soon "uplist" to the NASDAQ exchange.

138. Additionally, as set forth in Section V.B, Defendants also violated Section 10(b) and Rule 10b-5(b) by making materially false and misleading statements concerning the safety and efficacy of leronlimab to treat COVID-19, and the Phase 2 Trial (CD10) and Phase 2b/3 Trial (CD12). Indeed, in a May 17, 2021 Statement on leronlimab the FDA confirmed that: (i) "the data currently available do not support the clinical benefit of leronlimab for the treatment of COVID-19"; (ii) with respect to the Phase 2 Trial (CD10) "there was no observed effect of the drug on the study's primary endpoint or on any of the secondary endpoints," with "none of the secondary endpoints . . . met"; (iii) the Phase 2b/3 Trial (CD12) "also failed to find any effect of the drug on the primary study endpoint"; and (iv) "subgroup analyses" "do not support reliable conclusions about the medicine's benefit" "[i]f the analyses of the primary and secondary endpoints do not support conclusions of the medicine's benefit." Moreover, in a May 24, 2021

letter to Defendants, the SEC demanded that CytoDyn remove from its forthcoming Form 10-K for FY20 "language that states or implies that you believe leronlimab is safe and effective or that leronlimab is likely to be found safe and effective" "[a]s safety and efficacy determinations are within the authority of the U.S. [FDA]."

139. To date, the FDA has not made any determination as to the safety or efficacy of leronlimab for any indication and both the SEC and the DOJ are investigating CytoDyn and certain of its executives with respect to their "public statements regarding the use of leronlimab as a potential treatment for COVID-19 and related communications with the FDA, investors, and others and trading in the securities of CytoDyn."

1. Defendants Employ a Scheme to Defraud CytoDyn Investors with Respect to COVID-19

140. According to the SEC, "[m]icrocap stocks" like CytoDyn "may be particularly susceptible to stock promotion schemes," including pump-and-dump schemes. "Fraudsters who conduct stock promotions are often . . . company insiders who stand to gain by selling their shares after creating a buying frenzy and pumping up the stock price." The insiders create the "buying frenzy" by "mak[ing] false and misleading statements . . . and then quickly sell[ing] their shares before the hype ends." "The . . . insiders make profits for themselves while creating losses for unsuspecting investors."

141. The SEC has identified "red flags" and "warning signs of microcap fraud," including: (i) an "[i]ncrease in stock price or trading volume linked to promotional activity"; (ii) "[p]ress releases or promotional activity announcing events that ultimately do not happen (e.g., contracts expected to produce revenue never get finalized)"; (iii) the "[c]ompany issues a lot of shares without a corresponding increase in the company's assets"; (iv) the use of stock promotion and stock promotion services; and (v) "no history of operational success" but the company "still projects large future revenues, especially if the projections appear [to be] based solely on information about the company's industry rather than on the company itself." As

explained below and in Section VII.E, each of these "red flags" and "warning signs" were rampant before and during the Class Period at CytoDyn, supporting the fact that Defendants were perpetrating a fraudulent scheme.

142. More specifically, prior to the start of the Class Period, Defendants had put into place the infrastructure to create and capitalize on a buying frenzy manufactured by their false, misleading, and otherwise unsubstantiated statements and promotional efforts. *First*, Defendants materially increased the number of press releases they caused CytoDyn to issue. Historically, CytoDyn issued 30-40 press release in a calendar year. In 2019, the number of press releases CytoDyn issued approximately doubled to 70. In 2020, the number of press releases CytoDyn issued nearly doubled again to 130 and, during the Class Period, CytoDyn issued a record number of press releases. The press release generally contained at least one quote from Defendant Pourhassan, and often quotes from Defendant Kelly. Following these press releases, Defendants held conference calls with investors during which they expanded upon false, misleading, or otherwise unsubstantiated statements contained within the press releases. A significant amount of the information contained in these press releases and relayed during investor conference calls was never filed with the SEC and many of the events or milestones Defendants touted in their statements never came to fruition, *see* Section VII.E.

143. *Second*, despite CytoDyn's complete lack of revenues and millions of dollars of unpaid invoices, Defendants engaged (and paid hundreds of thousands of dollars to) numerous stock promotion websites and services. *See* Section VII.E. While Defendants utilized some stock promotion websites and services prior to the start of the Class Period, CytoDyn's own certifications to the OTCQB demonstrate that Defendants greatly expanded the use of these services during the Class Period. Defendants paid these outlets to, among other things: (i) reissue and amplify CytoDyn's press releases and investor calls; (ii) generate friendly interviews of Defendants that resembled materials generated by independent media outlets; (iii) host or otherwise moderate calls with investors and the audience of the promotional outlet; (iv) issue

biased articles and reports reflecting and expanding upon Defendants' false, misleading, or unsubstantiated statements and promotional efforts; and (v) respond to and counteract any negative press about leronlimab, CytoDyn, or the Individual Defendants. Because the disclosures of both CytoDyn and these websites regarding these promotional services were non-existent, vague, or buried, Lead Plaintiff will need discovery to uncover the full extent of Defendants' usage of stock promotion services before and during the Class Period.

144. *Finally*, Defendants issued to themselves millions in stock options and warrants just before the start of the Class Period—and sold millions of shares, netting themselves millions of dollars in profits, during the scheme. *See* Section VII.C.

145. Critically, Defendants' efforts to pump up the price of CytoDyn's common stock were not new. But in order to achieve the stock prices Defendants needed to cash in on their fraudulent scheme and to fund CytoDyn, they needed a catalyst, a story to sell to investors. The COVID-19 pandemic presented Defendants with a global emergency and, in the U.S., a national stage on which to conduct their stock promotion fraud. Moreover, due to the severity of the pandemic and lack of vaccines, treatments, or cures, regulatory regimes allowing for compassionate use and emergency approval or authorization in the U.S. and other countries, provided CytoDyn with a new shortcut to clinical use and, possibly, authorization (if not approval) of leronlimab that had eluded the Company for seven years. With this new potential indication and shortcut to regulatory approval, Defendants found a new means to pump up the price of CytoDyn common stock.

146. According to the SEC, "[f]raudsters often use the latest news developments to lure investors into scams." As explained in detail herein, Defendants are those fraudsters.

2. Prior to the Start of the Class Period, Defendants Purport to Explore the Use of Leronlimab to Treat COVID-19

147. CytoDyn issued the first of more than 150 press releases concerning COVID-19 on January 28, 2020, declaring that it was "exploring leronlimab as a potential treatment for

[COVID-19] patients." Defendant Pourhassan stated in the press release that he "look[ed] forward to advancing discussions with potential partners to study leronlimab as a [COVID-19] treatment option." Emerging Growth and Wall Street Reporter, two promotional outlets paid by CytoDyn, both re-issued and amplified this press release on their respective websites. Even though the January 28 press release said nothing concrete with respect to the use of leronlimab to treat COVID-19, the daily trading volume of CytoDyn's common stock increased nearly 60% immediately following the Company's announcement.

148. One week later, on February 4, 2020, the SEC's Office of Investor Education and Advocacy issued an Investor Alert titled, "Look Out for Coronavirus-Related Investment Scams." According to the SEC, it had "become aware of a number of Internet promotions . . . claiming that the products . . . of publicly-traded companies can prevent, detect, or cure coronavirus, and that the stock of these companies will dramatically increase in value as a result." The SEC warned, "[t]he promotions often take the form of so-called 'research reports' and make predictions of a specific 'target price.'" According to the SEC, "false statements relating to coronavirus may be about any company, microcap stocks may be particularly vulnerable to fraudulent investment schemes, including coronavirus-related scams." The SEC Enforcement Division joined the Office of Investor Education and Advocacy in reiterating these warnings on April 10, 2020.

149. Approximately 10 days after announcing that CytoDyn was "exploring" leronlimab as a potential COVID-19 treatment, Defendants intimated on a February 6, 2020 call with investors that they were looking for a partner in China to license leronlimab. Thereafter, on February 10, 2020, the Wall Street Reporter, a promotional outlet compensated by CytoDyn, held its "Next Super Stock Conference," featuring Defendant Pourhassan. When Wall Street Reporter's Jack Marks asked, "when do you think there will be any concrete announcement about the deal with China," Pourhassan replied, "we are about to announce something great about this."

150. That same day, another one of CytoDyn's paid promotional outlets, Emerging Growth, published a report authored by "admin" which touted the "China Licensing Deal," noting that Pourhassan had "indicated that they are working very closely with their Chinese counterpart to get the appropriate sign offs done to ink a non-binding deal." The report further speculated, "[w]hether its [sic] non-binding or not what is clear is that they are going through the appropriate channels like the Chinese FDA (cFDA) and that these channels are moving very quickly to get these trials started and completed." The report concluded, "[t]his could be the best lottery ticket you will ever buy. The drawing is in the next two months."

151. After hyping the market for days with respect to a potential Chinese licensing deal, on February 12, 2020, CytoDyn announced in a press release that it had signed a "nonbinding letter of intent (LOI) for the joint development and licensing of leronlimab in China with Longen China Group." Emerging Growth, Proactive Investors, and the Wall Street Reporter reissued and/or amplified this press release. During a February 24, 2020 interview posted on the Wall Street Reporter website Defendant Pourhassan confirmed that the "Longen Group" "is working with us right now to get" COVID-19 patients treated with leronlimab. Pourhassan further stated that CytoDyn was working on another unspecified letter of intent and term sheet and had been "approached . . . by other countries which we will be announcing very soon our agreement with them." Pourhassan further claimed that "we are now in talks with South Korea, Taiwan, [and] China."

152. On March 5, 2020, Defendants held a conference call with investors. During the call, Pourhassan stated the following with respect to Longen, China, and Taiwan:

> The next update is in regard to the anticipated timing of potential approval for TFDA Taiwan's FDA of leronlimab for the treatment of cancer[,] HIV[,] and coronavirus[.] [W]e have already signed a letter of intent and NDA . . . with a company which we are not naming at this time in Taiwan. . . . The next update is about doing the same kind of thing in China that we talked about in Taiwan we already have translated all of our documents that we gave to Longen Group and they already indicated that they have submitted it to ask so things and that record have already progress.

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> The next up update is an overview of doing licensing opportunities. We having licensing opportunities with several countries so in regards to Longen China group, which we announced, we signed a LOI Letter of Intent and NDA. Nine days from today the letter of intent will expire. So they are trying to finish up the final agreement, final term sheet and agreement which we have seen. We are working with them to finish as much as we can, fast as we can. . . . So in regards to the licensing agreement with another company which is a very solid company with financial background located in Taiwan. We will be announcing something shortly with them. We have signed LOI and NDA with them all so now both of these companies are right now talking to us to buy every bit of leronlimab that we have in commercial vials which is 24,000 vials . . . . [N]ow two different entity wants to purchase it and they want to also enter into an agreement to purchase the rest of that. This will come to the point where we will be short of the [vials] especially with coronavirus if we have positive results in the next few weeks hopefully.

153. On the same call, Dr. Bruce Patterson (Dr. Patterson),[7] a paid CytoDyn consultant, confirmed, "I was in China in January . . . and they were pleased to be able to talk to CytoDyn and no[w] hear about the possibility of bringing leronlimab over to China and now Taiwan . . . first . . . to address the coronavirus situation . . . ." Dr. Patterson further stated that "the HIV data and the cancer data" have "[a]ll . . . been submitted to both the CFDA in China and the TFDA in Taiwan as part of an ongoing process to get drug approval over there for coronavirus." With respect to the companies mentioned by Defendant Pourhassan, he stated that "we're very close to agreements with these companies and we'll be shipping drug to one other or the other or both in an effort to combat corona and ultimately cancer."

154. Ultimately, as explained below in Section VII.E, nothing ever came of the Longen LOI or, indeed, talks with South Korea, China, or Taiwan.

155. With its nonbinding LOI in hand, Defendants shifted to promoting their efforts to obtain FDA approval for leronlimab to treat COVID-19. In a March 9, 2020 press release CytoDyn announced that it had filed with the FDA an Investigational New Drug application ("IND") to conduct a Phase 2 clinical trial of leronlimab for treatment of COVID-19 in adult patients with mild-to-moderate COVID-19 symptoms ("Phase 2 Trial (CD10)"). Defendants also

[7] Dr. Patterson was the CEO of IncellDX, Inc. ("IncellDX"), a diagnostic company that provided technical support to CytoDyn starting in March 2019.

issued back-to-back press releases announcing that the FDA had granted CytoDyn an Emergency IND ("eIND") application and that four New York-based COVID-19 patients had been treated with leronlimab pursuant to the eIND.

156. Following these statements, CytoDyn's promotional machine began churning out content. First, Emerging Growth and Wall Street Reporter republished and amplified the March 9, 16, and 23, 2020 press releases on their respective websites. On March 9, 2020, Proactive Investors interviewed Defendant Pourhassan, posting the video clip styled as a news report to its website and YouTube. During the interview, Pourhassan presented leronlimab as "a solution to coronavirus" and claimed that in addition to sending the FDA "peer reviewed, published papers" regarding leronlimab's mechanism of action, "we are working with other companies right now . . . overseas for this problem." When asked by Proactive Investor "[h]ow it is possible that you're skipping to phase 2 efficacy trials" in COVID-19, Pourhassan touted the HIV safety results, speculating that "with that kind of data for [] safety that [the] FDA possessed from us, they always give us phase two very quickly . . . based upon all the data that we have gathered in the past." Pourhassan also speculated that CytoDyn was "far, far ahead" of Gilead, the maker of remdesivir, "because we have the product . . . ready to be shipped to whatever hospital that might need [it]."

157. Thereafter, Wall Street Reporter linked to a March 9, 2020 Yahoo! Finance "TipRanks" article titled, "A Treatment for Coronavirus? This Small Biotech is Working on It." Amplified by Wall Street Reporter, the TipRanks article pushed Defendant Pourhassan's narrative from the Proactive Investor interview one step further, claiming that CytoDyn would have "an edge vs. other therapies currently only undergoing preclinical testing" because of "the successful data on other indications for leronlimab."

158. The next day, March 10, 2020, Medical News First ("MN1") posted an article by Pat Monarch, titled "CytoDyn's Vyr[o]logix [leronlimab] to Fight COVID-19 – Hoping to Treat Phase 2 and 3 COVID-19 Patients." In addition to providing a rough transcript of Defendants'

March 5, 2020 call with investors, the MN1 article linked to a video of Josh Lankford ("Lankford"), co-founder of Lankford Media & Production Group, which owned and operated MN1, hyping CytoDyn and, in particular, the use of leronlimab to treat COVID-19. In May 2013, Lankford was sentenced to 84 months in prison for his role in a stock manipulation scheme whereby Lankford and his co-conspirators engaged in a "pump-and-dump" scheme with respect to the stocks of at least three companies, costing investors millions of dollars. MN1 later posted additional articles regarding CytoDyn and the use of leronlimab to treat COVID-19.

159. On March 19, 2020, Wall Street Reporter featured Defendant Pourhassan on a Next Super Stock livestream during which Pourhassan made similar statements about CytoDyn's efforts with respect to COVID-19. Then on March 23, 2020, an Emerging Growth report authored by "admin" further amplified and expanded upon Defendant Pourhassan's narrative concerning leronlimab's efficacy and safety for COVID-19. Specifically, in a section titled "Smoking Gun," the Emerging Growth report asserted that because leronlimab "stopped the trafficking of suppressor cells in cancer" and "[t]here is no difference in the Mechanism of Action (MOA) between the trafficking of suppressor cells in cancer versus a viral infection. . . . [I]nvestors who understand science will be able to predict a favorable outcome in days."

160. With respect to CytoDyn's eIND request, the Emerging Growth report further speculated that the FDA could upgrade CytoDyn's requested Phase 2 trial "to a Phase 3 trial" and concluded that "[b]ased on the anemic stock reaction many investors have not calculated that into their equation to buy" which "represents the opportunity" for investors. In its "Investment Summary" section the report further concluded: "Despite its very quick drug development CYDY investors just haven't been quick to grasp the ramifications of an approval in COVID-19. An approval would mean jumpstarting sales all across the globe. **The science supports a COVID-19 approval**. So investors with an appetite for risk should be bidding the stock up in anticipation of these compassionate use trial results." (Emphasis in original.)

3. Defendants Promote Leronlimab as an Efficacious and Safe COVID-19 Therapeutic as the Class Period Begins

161. On the first day of the Class Period, March 27, 2020, before the U.S. markets opened for trading, CytoDyn announced anecdotal "three-day results" for four of the seven New York-based COVID-19 patients receiving leronlimab under CytoDyn's eIND (hereafter, the "eIND Results"). A second press release issued 15 minutes later claimed that the FDA had asked CytoDyn to file a second Phase 2 trial protocol for severely ill COVID-19 patients ("Phase 2b/3 Trial (CD12)"). Before the U.S. markets opened for trading on the following Monday, March 30, 2020, CytoDyn issued a press release announcing that three additional New York-based COVID-19 patients had been treated with leronlimab pursuant to the eIND.

162. Again, Defendants' promotional machine sprung into action. First, Emerging Growth, Proactive Investors, and Wall Street Reporter re-issued and/or amplified CytoDyn's March 27 and 30, 2020 press releases on their respective websites. On March 27, 2020, Proactive Investor uploaded an interview of Defendant Pourhassan on its website and YouTube. During the interview, Pourhassan again touted CytoDyn's HIV safety data, stating "if we didn't have that, we could not be in the position we are with coronavirus." This statement (and similar statements made pre-Class Period) misleadingly implied that leronlimab was safe and, more specifically, that the safety results from the HIV studies meant that leronlimab also was safe to use to treat COVID-19. As the SEC reminded CytoDyn in a May 2021 letter instructing it to remove "language that states or implies that you believe leronlimab is safe and effective or that leronlimab is likely to be found safe and effective," "safety . . . determinations are within the authority of the U.S. Food and Drug Administration" and, to date, the FDA has made no such determination as to any indication for leronlimab.

163. The price and trading volume of CytoDyn's common stock increased by 91% and 240%, respectively, on March 30, 2020, representing a two-trading day increase in price and volume of 178% and 1,095%, respectively, from the price and volume reported on March 26,

2020. Moreover, the price of CytoDyn's common stock topped $2.60 on March 30, 2020—a price that CytoDyn had not seen since April 2012, nearly 8 years prior and several months before Defendant Pourhassan became CEO.

164. On March 31, 2020, Wall Street Reporter linked to a "TipRanks" article titled, "CytoDyn's Leronlimab Could Be an Answer to COVID-19." According to the TipRanks article, "the media finally caught up with the story" "about CytoDyn saying it could probably adapt its leronlimab drug to battle COVID-19." The article further stated that "if the growing number of patients being treated by leronlimab respond in similar ways [to the four New York-based COVID-19 patients], it's going to be an extraordinary boost to the value and share price of the company." The article also confirmed that Defendants' statements and promotional efforts with respect to COVID-19 "put CytoDyn on the map," "propell[ing]" the Company "into the national and international spotlight with the potential to successfully treat COVID-19." As explained in the TipRanks article, CytoDyn "is receiving the type of attention that has resulted in investors looking further under the hood of the firm, and so far they like what they see." The article further stated, "[i]n the short term COVID-19 will drive the share price of the company, but once further research reveals the significant potential of leronlimab in regard to a variety of diseases and symptoms, it could propel CytoDyn into being an elite player in the sector. It will of course also drive the share price far beyond where it stands today." The article concluded that CytoDyn "will never return to the obscurity it once operated under."

165. Over the following days and weeks, Defendants issued numerous press releases and other statements and paid promotional interviews, articles, and reports concerning the use, approval, and sale of leronlimab to treat COVID-19 patients in order to pump up the price of CytoDyn's common stock. Defendants' promotional efforts included unsubstantiated hype as well as false and misleading statements concerning: (i) the anecdotal results from the eIND patients, (ii) Phase 2 and 2b/3 Trials, (iii) the purported safety and efficacy of leronlimab in COVID-19 patients, (iv) the purported support of the FDA and the medical community's demand

for leronlimab, (v) the ability to immediately distribute (i.e., sell) leronlimab in the U.S., and (vi) the financing available to CytoDyn.

166. For instance, on March 31, 2020, CytoDyn issued two press releases within 15 minutes of each other, the first announcing that the FDA had cleared the Company's Phase 2 Trial (CD10) for mild-to-moderately ill COVID-19 patients, and the second announcing the completion of another convertible debt offering. With respect to CytoDyn's financing, the Company announced a "non-dilutive convertible debt offering with an institutional investor, which provides $15 million of immediately available capital." According to CytoDyn's then-CFO Craig Eastwood ("Eastwood"), the Company was targeting bringing leronlimab "to market" in 4Q 2020 or sometime between March and May 2021. As explained above in Section IV.D, CytoDyn entered into convertible debt offerings with onerous terms with a group of "vulture funds" run by John Fife (who is currently being investigated the SEC) in part because funding on more beneficial terms from more reputable funds was not available while Defendant Pourhassan remained CytoDyn's CEO. Further, without an FDA-approved indication, Defendants had no reasonable basis to project that CytoDyn would bring leronlimab to market by May 2021.

167. On April 1, 2020, in another press release, CytoDyn announced that it had filed a clinical trial protocol with the FDA for its Phase 2b/3 Trial (CD12). The press release quoted Defendant Pourhassan as stating, "[o]nce again, the FDA continues to be very supportive of everyone's efforts to increase access to leronlimab." The following morning before the trading day began, CytoDyn issued still another press release, this time claiming that "the three-day effect of leronlimab in eight severely ill COVID-19 patients [i.e., the eIND Results] demonstrated a significant improvement in several important immunologic bio-markers." According to Pourhassan, "our management team is focused to ensure we can distribute the drug across the country in a timely fashion."

168. Emerging Growth, Proactive Investors, and Wall Street Reporter re-issued and/or amplified each of these press releases on their respective websites and on March 31, 2020,

Proactive Investors uploaded an interview of Defendant Pourhassan to its website and YouTube. During the interview, Pourhassan touted the "green light" CytoDyn had received from the FDA as "a major milestone," stating that he was "very happy that the FDA has worked with us so quickly and able to expedite this since there was some positive results." He also touted the eIND results from the first four New York-based patients as "very strong."

169. Thereafter, on April 1, 2020, Wall Street Reporter linked to an interview Defendant Pourhassan gave to Adam Shapiro, Julie Hyman, and Anjalee Khemlani during Yahoo! Finance's "On the Move" show. During the interview, Pourhassan described the eIND Results from the first four patients as "spectacular" and touted the "three-day effect" noting that "the[se] results" demonstrate "an immunological benefit, which is a very strong result for us." Pourhassan also touted the Company's "very big start . . . with the FDA," which he claimed was due CytoDyn's treatment of "over 840 [HIV] patients with zero serious adverse events attributed to [leronlimab]" and leronlimab's purported lack of "toxicity or side effects." Pourhassan also claimed during the April 1 interview that "people in the finance community are believing that they need to get behind us. And we're getting quite a bit of offers of funding from different sources for our company." In reality, as explained in Section IV.D, the only funding CytoDyn could secure while Pourhassan remained CEO was from John Fife's "vulture funds."

170. On April 2, 2020, Proactive Investors posted an interview of Defendant Pourhassan to its website and YouTube. With respect to the Phase 2 Trial (CD10), Pourhassan described it as "the big one, because if we can give it to patients who are hospitalized but they have milder, moderate [COVID-19], we believe the results [are] just going to be fantastic." Pourhassan further claimed that CytoDyn was working with "so many hospitals" including "Harvard, Massachusetts General Hospital, Cornell, UCLA, San Francisco," because "[e]verybody wants to enroll now because they see that scientists are not shareholders. They look at this science . . . and they are convinced that this is really very strong."

171. Defendants' statements were at best unsubstantiated hype and at worst false and misleading. To date, the FDA has not made any determination of leronlimab's safety or efficacy in any indication, let alone COVID-19.

172. On April 1, 2020, the price of CytoDyn's common stock closed over $3.00 for the first time since December 21, 2011. During an April 2, 2020 interview with TD Ameritrade, when asked to "tell us why" CytoDyn's common stock has been "up 80 percent this week," Defendant Pourhassan touted the anecdotal results from the leronlimab eIND patients and the upcoming COVID-19 trials, and claimed, "we have something that is very promising and we can't wait to get the results from the clinical trial."

173. Defendants' barrage of COVID-19 related press releases and paid-promotional content continued. On April 6, 2020, CytoDyn announced that the first two patients in its Phase 2 Trial had received leronlimab and that it anticipated "initiating" its Phase 2b/3 Trial that week. Pourhassan confirmed that they hoped to send "the day three and day seven results of the first ten eIND patients to the FDA by the end of this week." A press release the next day, April 7, 2020, announced that "[t]he FDA recently cleared the Company to" start the Phase 2b/3 Trial "for which enrollment is now underway." Pourhassan further claimed that CytoDyn was working "to establish similar expanded access (emergency use) programs for leronlimab for the treatment of COVID-19 with other governmental regulatory authorities." As was often the case with Defendants' promotional efforts, these statements provided no specifics, including to which governmental regulatory authorities Defendants referred, making them unsubstantiated hype. Moreover, as explained in Section VII.E, many of the events, actions, and milestones Defendants touted during the Class Period still have not come to fruition.

174. On April 9, 2020, CytoDyn issued a press release touting anecdotal results from compassionate use of leronlimab, claiming that "[c]ritically ill patients are experiencing the benefit of extubating within 7 days of treatment with leronlimab." In the same release, Defendant Pourhassan further stated that "leronlimab appears to facilitate an immunological restoration in

these patients and we are sharing our data with the FDA in order to hopefully accelerate the access of our drug to many more patients in need." Thereafter, in a press release on April 13, 2020, CytoDyn provided a purported "comprehensive update and overview . . . from over 30 COVID-19 patients recently treated with leronlimab." On April 14, 2020, Pourhassan appeared on One America News Network to tout leronlimab for COVID-19. Then, on April 15, 2020, CytoDyn announced that the first patient had been treated in its Phase 2b/3 Trial (CD12).

175. Emerging Growth and Proactive Investors reissued and/or amplified each of these press releases on its own website. For its part, Proactive Investors, posted ***five*** successive interviews of Defendant Pourhassan dated April 6, 7, 9, 13, and 15, 2020, on its website and YouTube, each of which provided Pourhassan and CytoDyn with a platform to pump up the price of CytoDyn's common stock. For instance, at the outset of the April 6, 2020 interview, Proactive Investors asked Pourhassan about CytoDyn's common stock "rally" to $2.89 per share, to which Pourhassan responded, "it's justifiable. And I'm hoping to have a lot higher prices." With respect to the anecdotal eIND results, Pourhassan touted the "amazing seven day data."

176. During the April 7, 2020 Proactive Investors interview, Pourhassan stated, "we have major news for me to announce . . . we have seen amazing data coming out. We are taking patients out on a ventilator . . . [a]nd to see them recover[,] self extubate[,] I mean, that's major for us and we're very excited about it." Pourhassan continued, "we're going to be focusing on publishing immediately in the New England Journal of Medicine" and "giving [that data] to [the] FDA very quickly."

177. Thereafter, during the April 9, 2020 Proactive Investors interview, Pourhassan claimed that he was "reaching out to Anthony Fauci as soon as possible and the FDA myself, because these results are – there is no joke here. Now, this is something that has been very, very carefully analyzed. These patients show immunological benefit." Later in the interview,

Pourhassan claimed that "Dr. [Jacob] Lalezari," CytoDyn's then-interim CMO,[8] "is reaching out to just show the data, because Dr. Anthony Fauci, Sanjay Gupta [a CNN expert], they all want data, and they don't want to talk about how good we can do. And now we have human data . . . ." Additionally when asked during the April 13, 2020 interview by Proactive Investor for an "update on some of those patients" "who have been treated with leronlimab," Pourhassan claimed, "we have seen strong results . . . [a]nd [the] FDA [is] working with us in a great way."

178. Then, on April 17, 2020, Wall Street Reporter held a Next Super Stock Livestream featuring Defendant Pourhassan and Dr. Lalezari. The livestream was posted on the Wall Street Reporter website and YouTube. During the livestream, again speaking on behalf of CytoDyn, Dr. Lalezari claimed that "the world has missed this [using leronlimab to treat COVID-19] . . . from the get go" and "it's taken us many weeks and a couple of months to get FDA caught up as to why this makes sense." Dr. Lalezari further speculated that "when the . . . full data set . . . is published, the entire world will understand why this makes sense." Dr. Lalezari concluded that while "it is a bizarre thing at this moment that leronlimab isn't higher on the list" "CytoDyn is going to get a lot more exposure." Pourhassan described "the early clinical results" as "pretty spectacular," noting that "our data is strong" and the "science is solid behind it." With respect to the FDA, Pourhassan "credit[ed] the FDA big time on this" and intimated that the agency "saw that there is something" in the data which led the FDA "to expedite[] our Phase II immediately."

179. Despite Dr. Lalezari's claim that "CytoDyn is going to get a lot more exposure," Defendants' avalanche of promotional efforts with respect to the use of leronlimab to treat COVID-19 were not continuing to have the desired effect on CytoDyn's stock price. In an internal April 14, 2020 e-mail, Defendant Pourhassan wrote to Amarex that "[t]oday we have so

[8] On March 13, 2020, CytoDyn announced that Dr. Jacob Lalezari ("Dr. Lalezari") was appointed as Interim CMO. As of October 2020, Dr. Lalezari was no longer the CMO and CytoDyn represented that he was "Senior Science Advisor."

far in 1 hour almost 20% drop in our stock price. Yesterday [April 13, 2020] we had drop also after putting out great results about COVID-19 patients we are seeing these type of decline." Pourhassan also confirmed that "the message board now is getting bombarded by investors who are very frustrated with me and CytoDyn." Pourhassan went on: "[t]his [stock price] drop will be much deeper if we don't file our BLA . . . . Please file the BLA no later than next Wednesday [April 22, 2020], even if we are short in no matter what portion of whatever it is that we are short." Pourhassan concluded by stating "COVID-19 is no longer CytoDyn's top priority as if the stock continues its drift then financially we will have problems financing [CytoDyn]. The MOST IMPORTANT thing now is [the] BLA. Please focus on that urgently only."

180. Consistent with Pourhassan's directive, CytoDyn filed a materially incomplete HIV BLA on or before April 27, 2020, to disastrous effect. Within a few months, the FDA refused to file the application, noting to CytoDyn that the HIV BLA lacked a variety of safety and efficacy data and information the FDA had expressly told CytoDyn must be included for the HIV BLA to be deemed complete.

4. As Defendants' COVID-19 Promotional Efforts Continue, Defendants Pourhassan and Kelly Sell $20.5 Million in CytoDyn Common Stock

181. After knowingly filing a materially incomplete HIV BLA on or around April 27, 2020, Defendants doubled-down on their scheme to pump up the price of CytoDyn's common stock by touting leronlimab for COVID-19, with Defendants Pourhassan and Kelly brazenly cashing in, selling millions of Company shares for proceeds of more than $20 million beginning April 30, 2020.

182. On April 24, 2020, CytoDyn issued a press release announcing that it would update investors on its HIV BLA and COVID-19 efforts on the next trading day, April 27, 2020. The price of CytoDyn's common stock rose 16% and the trading volume nearly doubled from the prior trading day. Then, during an April 27, 2020 conference call, Defendant Pourhassan stated, "[t]o have a solution against COVID-19 is to save humanity from a powerful plague . . .

and that brings us to today's most powerful news of CytoDyn's history. In the past, I thought . . . that the BLA filing would be the biggest news of CytoDyn's history. . . . We have news that is by far much larger than the BLA. So allow me to update you on our fight against COVID-19 with leronlimab." Specifically, Pourhassan claimed that "[b]lood sample analysis of the first [New York-based COVID-19] patients . . . revealed some exciting news." Pourhassan described the results as "impressive" and, later, "remarkable," and claimed that "we expect probably several publications surrounding these findings to be out in the next few days and weeks." With respect to the FDA, Pourhassan further stated, "[w]hen 200 companies run to [the FDA and] say, 'hey, we got the solution to coronavirus! Please say something positive so our stock can go up,'" the FDA "get[s] worried" but "they have given us everything we have asked for."

183. On April 27, 2020, the price for CytoDyn's common stock rose another 17% and the trading volume rose another 80%, for a two trading day (April 24 & 27) price increase of 33% and volume increase of 170%.

184. Following the success of Defendants' COVID-19 promotional efforts after the HIV BLA filing, the parade of press releases continued. On April 30, 2020, CytoDyn issued a press release touting "strong results from eIND COVID-19 patients treated with leronlimab." Per CytoDyn, "54 eINDs [have been] approved by [the U.S.] FDA and 49 patients have been treated with leronlimab this far." With respect to "Eleven (11) Patients in NY hospital," which appear to include the 10 New York-based patients identified by CytoDyn in March 2020 of which at least "six patients were renal-transplant recipients," CytoDyn reported that the Company was "able to save the lives of four patients."

185. In the same press release, CytoDyn reported that "important powerful results from the effect of leronlimab were demonstrated in almost all of these patients," and "[t]his data has been submitted to a prestigious journal and ***we expect the publication on Friday, May 1***." Defendant Pourhassan touted the upcoming publication as "our first major paper very close to publication" and hinted at another publication "shortly thereafter." However, no article was

published on May 1, 2020 and, on May 6, 2020, CytoDyn announced that "***pre-print version of the manuscript*** has been made publicly available on posting with Research Square and MedRxiv" but conceded that the manuscript had only "been submitted for publication" and was "currently under peer review."

186. Meanwhile, Defendants' paid promotional outlets were hard at work. Emerging Growth and Proactive Investors reissued and/or amplified CytoDyn's press releases. On April 30, 2020, Proactive Investor uploaded an interview with Defendant Pourhassan on its website and YouTube. During the interview, Pourhassan touted the eIND results as "really, really amazing," claiming that before these results, CytoDyn was "not given a green light from the FDA to go to [a] phase two [trial] because . . . we didn't have any animal[studies]," but "when the first one of those two [New York-based COVID-19] patents self-extubated . . . that started to make the FDA feel more relaxed," such that the regulator agreed to the Phase 2 and Phase 2b/3 Trials. He further claimed that CytoDyn was "reporting almost 95% or so rate of [eIND] patients being alive and doing better and improved . . . that's a spectacular result[]. And we wanted to make sure everybody knows that." In a subsequent May 6, 2020 Proactive Investor interview, Pourhassan claimed that "Dr. Patterson has . . . statistically significant data that means he took the blood of these [eIND] patients and showed why leronlimab work[s]. That should put a lot of doubters' minds at ease that, hey, the mechanism of action is clear."

187. On May 1, 2020, Wall Street Reporter held a "Next Super Stock" livestream in which Defendant Pourhassan and Dr. Patterson participated. When Wall Street Reporter's Jack Marks asked Pourhassan, "[w]hy is it so hard for the FDA to realize how many lives can be saved by using leronlimab?" Pourhassan replied, "please don't point fingers at [the] FDA at the time that they're doing a fantastic job separating two hundred companies from the real to fiction. ***Obviously, they believe that we have something here***. That's why they've been giving us face to face . . . and approval left and right . . . one after another." Further, with respect to the eIND anecdotal results, Dr. Patterson stated, "we're looking at the data on how the drug works on

COVID and saying, hey, the drug is doing what it's supposed to be doing and that's statistically significant. So we have great, great confidence that because it's been embedded into the trial design that we're going to have a positive outcome."

188. It was at this point, when their hype of leronlimab as a potential COVID-19 treatment was at a fever pitch, that Defendants Pourhassan and Kelly began to dump their shares of CytoDyn common stock. *See* Section VII.C. Plaintiffs traded contemporaneously with Pourhassan and Kelly, buying shares of CytoDyn common stock as Pourhassan, in particular, exercised 11 years-worth of options and warrants—including options and warrants he and Kelly had improperly granted themselves in December 2019.

5. Following the May 2020 HIV BLA Disclosure, Defendants' Promotional Efforts with Respect to COVID-19 Go into Overdrive

189. On May 4, 2020, CytoDyn announced that its HIV BLA was not, in fact, complete as Defendants had represented on April 27, 2020—although it misleadingly offered words of assurance and asserted the BLA would be complete in a matter of days, after a follow-on submission. CytoDyn ultimately submitted additional information to the FDA in support of its HIV BLA on May 11, 2020, representing that the submission was purportedly ***now*** complete. Accordingly, Defendants turned their attention back to pumping up the price of CytoDyn's common stock via false, misleading, or unsubstantiated statements and promotional efforts concerning the use of leronlimab to treat COVID-19.

190. On May 18, 2020, CytoDyn issued a press release announcing that it was "prepar[ing]" to submit to the FDA a Phase 3 protocol for a combination trial of leronlimab and remdesivir to treat COVID-19. According to Pourhassan, "CytoDyn has assurance from its manufacturer that it will have available over 1 million vials this year and could ramp up production to 2-3 million vials this year alone." In the same press release, the Company stated that it "plan[ned] to update the public regarding current eIND results later this week." Proactive Investors reissued and/or amplified these press releases on its website.

191. Proactive Investors also posted an interview of Defendant Pourhassan on its website and YouTube on May 15, 2020. During the interview, Pourhassan speculated that the Phase 2 Trial results were "going to be very exciting results" and that "[h]opefully we will be the second product that has great results and be able to go forward with [FDA] approval." In response to a Proactive Investor question, "do you think this could be the next big thing? It seems like you're fairly confident," Pourhassan stated, "we think it's going to be a very big."

192. In a subsequent Proactive Investor interview posted to YouTube on May 18, 2020, Pourhassan further stated, "our own Trial Phase 2, which we believe the results of that would show to everybody what we have. And we think the results are going to be very impressive." In another Proactive Investor interview posted to YouTube on May 20, 2020, Pourhassan asserted CytoDyn was "going to really crush the primary endpoint [of the COVID-19 trials]" because of the eIND Results, claiming "we have data that shows that we are going to be successful with this." Also on May 20, 2020, Wall Street Reporter hosted Pourhassan on its Next Super Stock livestream where he made similar comments about CytoDyn's COVID-19 data.

193. Thereafter, on May 21, 2020 Emerging Growth posted a "report" regarding Sorrento Therapeutics authored by "admin" ostensibly about Sorrento's COVID-19 "cure." However, the Emerging Growth report concluded that given that Sorrento "does not have a cure" for COVID-19, a Sorrento shareholder's "best course of action might be to avoid the drama and invest in the only drug doing a head to head comparison to remdesivir," leronlimab—"a drug that has been used in over 800 patients in HIV, filed its BLA to likely become an approved HIV drug in 6 months, and has a non-toxic profile with no exclusion criteria for COVID-19."

194. On May 29, 2020, Emerging Growth again posted a "report" seemingly about one company with a COVID-19 therapy, ARCA Biopharma, but concluding that "[t]he most promising treatment in development is CytoDyn's leronlimab. This is a drug with an incredible safety profile of 800+ patients without any SAE's related to the drug." The Emerging Growth report continued, "[f]or the most part this drug has been ignored by the administration and been

given marching order to complete the trial. Its expected enrollment will be completed in two weeks so speculation of the most important regulatory action to take place on the planet is largely being ignored by investors. CYDY will be the next to readout on a COVID-19 therapy and preliminary journal articles indicate it works." The Emerging Growth concluded, "[a]head of [ACRO Biopharma] in the COVID-19 race is CYDY with their monoclonal antibody in the top slot about to overtake GILD and remdesivir . . . but as an investor there is clearly more potential in CYDY if you are looking to capitalize on a COVID-19 treatment."

195. Defendant Pourhassan touted the impact of Defendants' promotion scheme on CytoDyn's common stock during a May 26, 2020 investor conference call, claiming CytoDyn's "market cap is about $1.4 billion and we are trading at the historical volume levels," claiming "[t]hat is probably a world record for U.S. companies." He further stated, "in the last six months alone, we have traded more than $1.2 billion dollars, four times more than all the previous 11 years put together[;] 400% more in just the past six months than the previous 11 years."

196. Defendants' false, misleading, and unsubstantiated statements and promotional efforts regarding the use and regulatory approval of leronlimab to treat COVID-19 continued throughout the summer of 2020.

197. For instance, on June 2, 2020, Wall Street Reporter held another Next Super Stock livestream event featuring Defendant Pourhassan. During the livestream (which was posted on the Wall Street Reporter's website and YouTube), Pourhassan claimed that "the unblinding" of the Phase 2 Trial data would occur "very much likely on June 15th" and the "primary endpoint would be read out to the world." Pourhassan further confirmed that Defendants "hope[d] to shock the world with the very beautiful results."

198. Later in the same interview, when Wall Street Reporter's Jack Marks asked whether Dr. Fauci was "aware of leronlimab?," Pourhassan responded, "I have no idea, Dr. Fauci," but the "FDA and so forth, they want to see results" and "I'm sure if they get the results that we think we're going to get, it will be very happy for us." Pourhassan later described

the results as "astonishing." When Marks asked Dr. Lalezari where he "envision[ed] leronlimab will rank in comparison to all time successful drugs," Dr. Lalezari responded, "if we look at the rest of the COVID-19 landscape, there's no other drug that is showing this kind of antiviral effect. . . . So, yes, it is utterly amazing how well and that effect is being seen in 100 percent of patients." He further asserted, "the world has never seen anything like [leronlimab]" and "yes, this story is going to have a huge impact. And my biggest concern would be making sure there's enough drugs to treat. Everybody in the world is going to need it."

199. On June 5, 2020, Proactive Investor posted another interview of Defendant Pourhassan on its website and YouTube. During the interview, Pourhassan claimed that because "there is no difference between [the] safety" data for HIV and COVID-19, "with COVID-19" all CytoDyn needed to "show" was "efficacy" to "be good to go."

200. Thereafter, on June 11, 2020, CytoDyn issued a press release announcing that it had completed enrollment in its Phase 2 Trial (CD10). Proactive Investors once again reissued and/or amplified this press release on its website. That same day, Defendants held a conference call with investors. During the call, Pourhassan claimed that, if the COVID-19 trials are "successful," given that CytoDyn already has demonstrated safety (i.e., "our safety has been generated in HIV population for more than 900 patients"), "then we are ahead of everybody [else with a COVID-19 therapeutic] because everyone else has to do safety." In the same call, Pourhassan claimed that when CytoDyn shared the data on the first 11 eIND patients with the FDA, "the FDA rightfully so, they said, great, good job."

201. On June 12, 2020, Emerging Growth posted on its website a report authored by "admin" titled, "Adam Feuerstein's Fishing Expedition on CytoDyn (CYDY) Continues to Cast an Empty Net." The report asserted that "[i]t's very clear that leronlimab works and even clearer that the results will confirm what was seen in the [eIND Results]," claiming that it was "almost [an] undeniable fact that the drug works." With respect to the likelihood of the FDA's approval of leronlimab to treat COVID-19, Emerging Growth claimed that "[t]he FDA has sent a very

strong signal that approval is weeks away. There is a chance it could take longer, but given the incredibly weak data that won remdesivir an FDA emergency approval it's reasonable to think that this is a shoe in." With respect to future leronlimab sales, the report stated that CytoDyn—a company with no history of operational success—"expects to produce 1.5 million vials of leronlimab in the next half of 2020 for 375,000 patients," generating "$2.5 billion in sales this year," and "an estimated 6 million vials" for "$9.0 billion in revenue" in 2021 "if leronlimab receives regulatory approval." The report concluded that "[i]t's astonishing how undervalued this stock seems to be. . . . With close to $12 billion in revenues likely in the next 1.5 years investors need to ask why the stock is trading at a 90% discount to just one times sales. . . . This is in pole position to be the first FDA approved drug to treat COVID-19."

202. A subsequent Emerging Growth report on CytoDyn authored by "admin" published on July 1, 2020 concluded that "[t]here are many catalysts going forward that could make this the next Gilead Sciences" including "[i]nterim clinical trial results from 50 patients in the phase 3 severe COVID-19 should be out within the next 2 weeks," "[t]he Mild to Moderate trial should be completed and ready to be unblinded once all the data is collected," "[t]he COVID-19 opportunity represents $2.5 billion to $9.0 billion in the following year," and "[t]he Mexican Memorandum looks very positive and appears to have the least regulatory hurdles to jump over to make it to registration." But, the most "unnerving catalyst for the shorts," according the Emerging Growth report, is "an uplisting to a major exchange. The increased liquidity and greater regulatory oversight should make conditions more difficult for shorts to exploit."

203. Beginning on June 18, 2020, the closing price of CytoDyn common stock increased on eight consecutive trading days, with similarly large increases in trading volume. For instance, over June 18 and 19, 2020, the price of CytoDyn's common stock increased nearly 20%, with trading volume increasing 400%. Then, on June 22, 2020, CytoDyn's common stock closed above $4.00 per share for the first time since December 2011. On June 23, 2020, CytoDyn's shares closed at the highest price ever, $4.48. On June 25, 2020 and again on June 26,

2020, CytoDyn's common stock closed above $6.00 per share for the first time ever—a record smashed one trading day later, June 29, 2020, when CytoDyn's stock closed at $8.77 per share, eclipsing the highest pre-COVID-19 close by nearly 100%. While a June 30, 2020 Citron report took some wind out of the sails of CytoDyn's common stock, the shares rebounded to close at $6.48 per share on July 1, 2020. At this point, Defendants began the application process to uplist CytoDyn's common stock to the NASDAQ exchange.

6. NASDAQ Uplisting Provides Defendants with Additional Incentive to Inflate the Price of CytoDyn's Common Stock

204. "Uplisting" CytoDyn's common stock, which then (and now) traded OTCQB under the ticker CYDY, to the NASDAQ exchange was not a new concept in June 2020. For instance, during an April 27, 2020 investor call, Defendant Mulholland discussed the criteria for NASDAQ uplisting: "there's three quantitative criteria that we've got circled and have been totally dialed-in on these last couple of years. . . . [N]umber one, is the stock price: needing to meet the minimum threshold for . . . NASDAQ. Number: two, sufficient levels of positive stockholders' equity at the time of uplist, and lastly, . . . anywhere from twelve to eighteen months of projected cash requirements on the balance sheet at the time [of uplisting]." Mulholland further claimed, "as we move forward, we're checking off the list, and we're making some great progress."

205. On May 13, 2020, Wall Street Reporter held a Next Super Stock livestream featuring Defendants Pourhassan and Mulholland. During the livestream (which was posted both on Wall Street Reporter's website and YouTube), Mulholland again spoke about when CytoDyn would "uplist," and confirmed: "we now have continuing strong clinical results, coupled with a strengthening stock price, both of which support our priority to effect an uplist."

206. Following the run up in CytoDyn's stock price in June 2020, during a July 4, 2020 interview with Dr. Mobeen Sayed, a/k/a Dr. Been, who provided a subscription based site that shows medical-related videos, Defendant Pourhassan claimed that CytoDyn now had the

stock "price that can qualify us for NASDAQ." Pourhassan also suggested that "the special situation with pandemic requires special actions, and we are asking to hopefully not to have to – for us not to meet the funding requirement of uplisting. So we're waiting for that right now."

207. During a July 13, 2020 conference call with investors, Defendant Mulholland announced "that earlier today, we've completed our submission of a multi-part application for NASDAQ." In response to a question from Pourhassan—"the requirement for NASDAQ is between 3 dollars and 4 dollars. They both are approvable to go to NASDAQ. What's the difference?"—Mulholland responded that CytoDyn was "in good shape"; "I'd say that we meet — we have no issues on the other standards. And if we look at the stock price, if at the time of uplist, the stock is at $4.00, we're fine. If by chance, the stock should soften . . . down to . . . $3.00 or above, . . . we're still fine, because we meet the net tangible assets standard." Mulholland also stated, "this could be about four to six-week process" and confirmed that NASDAQ "is going to want to see our . . . 10-K," which was due to be filed August 14, 2020.

208. On July 15, 2020, CytoDyn issued a press release announcing that it had "recently filed a comprehensive listing application with The Nasdaq Stock Market to request an uplisting of the Company's common stock." The press release further stated, "The Company believes it satisfies the initial listing requirements for The Nasdaq Capital Market."

209. If it had been successful (it was not), a NASDAQ listing would have brought CytoDyn (and Defendants) a much larger, potentially more institutional investor base and, critically for Defendants' ability to capitalize on their stock promotion scheme, access to far more liquidity than was typically available in the OTC market. During a July 15, 2020 Proactive Investor interview when asked "why now?" with respect to uplisting, Pourhassan stated, "we think everything is coming together in a beautiful way for us. We wanted to have the stock to go to a different level with all this stuff that we have. I mean, it's rightfully so . . . things are happening in a spectacular way now. And to put the finishing touches is uplist to the NASDAQ."

Pourhassan further claimed, "[w]e feel very comfortable. We meet all the criterias . . . we will do whatever it has to be done to make us a NASDAQ company."

210. And regardless of whether they could raise additional funds to address the NASDAQ uplisting requirements tied to assets and shareholders' equity, Defendants also had to maintain the price of CytoDyn's common stock above a $3.00 per share closing price or above a $4.00 per share bid price in order to uplist. Accordingly, Defendants' false, misleading, and unsubstantiated statements and promotional efforts with respect to COVID-19 took on a new urgency—maintaining the threshold price for CytoDyn shares—and Defendants' fusillade of press releases and paid-for interviews, conferences, articles, and investor reports continued unabated. As explained herein, ultimately, Defendants' efforts to uplist to the NASDAQ were not successful and, following the disclosure of the relevant truth, *see infra* Section VI, CytoDyn's common stock currently trades around $1.00 per share.

7. After Weeks of Hyping the Phase 2 Trial (CD10), Defendants Concede the Trial Has Failed to Meet Its Primary Endpoint

211. After hyping the results of CytoDyn's first COVID-19 trial of leronimab, the Phase 2 Trial or CD10, for weeks, Pourhassan confirmed on July 17, 2020 that the Phase 2 Trial test results were "unblinded now." The next day, July 18, 2020, during an interview with Dr. Been that was posted to YouTube, Pourhassan specifically confirmed that the Phase 2 Trial data was unblinded and "with Amarex" and that he was "hoping to be able to get results on Monday [July 20, 2020] and have a press release on Tuesday [July 21, 2020]." Pourhassan further speculated, "if we get beautiful results right now, I think the whole world will pay attention."

212. On July 20, 2020, Emerging Growth published a report authored by "admin" echoing Defendant Pourhassan's weekend statements to Dr. Been. Per Emerging Growth, "[t]he anecdotal data from 75+ emergency IND patients is overwhelming in favor of this drug working and the safety is beyond reproach." Near term catalysts for CytoDyn's stock price included, a

"NASDAQ uplisting in the coming month," and "[t]he first COVID-19 readout is due Tuesday and by all measures it looks primed to be extremely positive . . . offer[ing] explosive upside with very little downside risk." Emerging Growth further stated: "[i]f the results are spectacular, the stock is likely to climb to new heights," comparing it to "Gilead's [stock] price movement in response to a potential COVID-19 treatment," a $10 billion increase "in just one day," which "translates into a $20/share price gain" for CytoDyn common stock "based on valuation alone."

213. On the trading day after Defendant Pourhassan's interview with Dr. Been, the price of CytoDyn's common stock rose 16% and its daily trading volume rose more than 50%.

214. On July 21, 2020, CytoDyn issued a press release touting "impressive results" from the Company's Phase 2 COVID-19 trial. Proactive Investors reissued and/or amplified this press release on its website. Despite having access to both efficacy and safety data, Defendants chose to tout only the patient safety data, claiming that they still needed to complete "the statistical analyses of all primary and secondary endpoints." According to the July 21 press release, "34% (19 of 56 patients) treated with leronlimab compared to 50% (14 of 28 patients) treated with placebo reported at least one adverse event" and with respect to 19 serious adverse events (SAEs), there were more reported with the placebo (11) than with leronlimab (8), and "[n]one of the SAEs in the leronlimab arm were deemed related to study drug administration by the investigators." In the press release Defendant Kelly emphasized leronlimab's purported safety record, noting that while patients taking leronlimab experienced fewer SAEs than patients taking the placebo, "[p]rior drugs in clinical trials for the treatment of COVID-19 [i.e., Gilead's remdesivir] have resulted in an increase in SAEs in the drug treated arm versus placebo."

215. That same day, Proactive Investor posted an interview of Defendant Pourhassan on its website and YouTube. During the interview, with respect to the Phase 2 Trial (CD10) results, Pourhassan claimed that "what is missing," e.g., the efficacy data, "is amazing." Pourhassan further claimed that the Phase 2 Trial (CD10) safety data "itself could be an efficacy for us because . . . that's a fantastic result." Pourhassan continued, "people in the world will now

start catching up and we're going to have more data putting out and they're going to realize that we are very serious about getting approval for leronlimab." With respect to the Phase 2 Trial (CD10) efficacy data, Pourhassan said CytoDyn had "something that could shake the world" and that the delay in releasing the efficacy data was due to his "regulatory team and biostatiscian" requesting "time to put this in the right format."

216. During a special meeting of CytoDyn's shareholders on July 22, 2020, Defendant Pourhassan claimed "we are very close to be able to submit some solid data [for] our therapy for COVID-19 to the FDA for consideration — for final approval in two separate populations: mild–to-moderate . . . critical and severe." Pourhassan continued, "[w]e will stay visible, transparent, and we will report honestly everything that happened in our company as frequently as possible, like usual." Pourhassan went on, "we can't wait to put out the efficacy results" adding, "we will send to the FDA the whole package [of Phase 2 Trial (CD10) data] and request emergency approval for this indication based on unmet medical need — the nature of this pandemic that we're living right now . . . we might be a few weeks away from potential approval."

217. Continuing the promotional flood, on July 30, 2020, Defendants held an investor conference call. With respect to the CD10 results, Pourhassan stated: "we do have positive efficacy results. . . . In regards to our primary endpoint, . . . [w]e have seen improvement in day 3 versus day zero." With respect to the NEWS2 (National Earning Warning Score 2 scale) endpoint, Pourhassan stated, "we are *so* delighted with these results." (Emphasis in original.) Pourhassan continued, "we are still evaluating a mountain of information to put in our exciting top-line report and present to the FDA as soon as possible. . . . We hope to have the top line report within 10 days or so."

218. Additionally, during the call, Pourhassan claimed that "no one has ever received any positive efficacy results better than placebo in this population in a randomized double-blinded FDA trials." Pourhassan claimed, "you just heard a fantastic result that nobody has heard, even FDA doesn't have that." He also called the results "excellent." Further, when asked

by a call participant to clarify whether the trial results were "mixed," Pourhassan claimed "those results that we're seeing are very strong, and we can't wait to put in a press release."

219. That same day, Emerging Growth published a report authored by admin titled, "CytoDyn's (CYDY) 100% Above Market Offering Stuns the Street." With respect to the Phase 2 Trial safety data, the report claimed, "[t]he market has really been disconnected from reality with respect to its comprehension of the safety data . . . the safety data from the CD10 trial was jaw dropping . . . leronlimab was about as safe as drinking water." According to Emerging Growth, "**[t]he lack of SAE's is an absolute indication of efficacy and likelihood that they met their primary endpoint**. In ANY randomized double blind placebo controlled study a reduction in SAE's . . . could be a consideration for approval." (Emphasis in original.) The report concluded, "[i]nvestors need to wake up and realize that CYDY won the game."

220. On July 31, 2020, Proactive Investors interviewed Defendant Pourhassan and posted it on its website and YouTube. During the interview, Pourhassan stated, "[w]e have a product that has shown very strong results . . . . Today we have to all look for positive things that any drug can do and be united. And what we have right now" is "a very positive result" for the National Earning Warning Score 2 scale, a secondary endpoint of the Phase 2 Trial, "we think we had a jackpot with that." Pourhassan claimed, "[i]n regards to [the] [P]hase 2 [Trial], this is not a primary endpoint hit or miss . . . phase 3 is where it's do or die."

221. On August 11, 2020, CytoDyn issued a press release 15 minutes into the trading day, announcing Phase 2 Trial or CD10 "top-line" results, calling them "clinically significant." Proactive Investors reissued and/or amplified this press release on its website. In the release, CytoDyn noted that leronlimab did not achieve the primary endpoint. Specifically, CytoDyn reported that the primary endpoint of the Phase 2 Trial (CD10) "show[ed] early clinical improvement in symptom score at Day 3 in patients receiving leronlimab" and that "leronlimab also demonstrated statistically significant improvement versus placebo in [a] key secondary efficacy endpoint, National Early Warning Score 2 scale (NEWS2)." The press release quoted

Pourhassan as follows: "Patients receiving leronlimab showed a statistically significant improvement using NEWS2 clinical parameters. We will make a case for immediate approval of leronlimab for this population of COVID-19 patients, not only in the U.S., but in the U.K. and other countries around the world." The press release also quoted Defendant Kelly stating, "The decreased probability in serious adverse events, as well as overall adverse events with leronlimab compared to placebo further supports the use of leronlimab as a treatment option for COVID-19."

222. The fact that CytoDyn had missed the primary endpoint for the Phase 2 Trial was not lost on the market, with the stock price declining throughout the day on August 11, 2020. In response, Defendants rushed to prop up the price, issuing a same day press release 20 minutes before the close of trading announcing a conference call the following day, August 12, to discuss the "impressive" and "compelling" Phase 2 Trial (CD10) results and to provide "an update" on the Phase 2b/3 Trial "and the regulatory path going forward." Despite Defendants' spin and promotional efforts, the price of CytoDyn's common stock declined 14% while trading volume increased nearly 200% from the prior trading day.

223. During the August 12, 2020 investor conference call, Pourhassan announced that, "[a]s of about an hour ago, CytoDyn has requested from the FDA to grant CytoDyn an emergency use authorization for leronlimab based on CD10 data." He further claimed, "we are very excited to file for emergency use authorization in many different countries." However, Pourhassan was forced to admit that the Phase 2 Trial (CD10) had not met its primary endpoint:

> Did we meet our primary endpoint? Meeting your primary endpoint – that means you have a clinically significant value, and if . . . the value is much better in the drug versus placebo, then that becomes statistically significant. If it's not statistically significant, but clinically significant, then your Phase 3 will do the same thing as Phase 2, but with a higher number of patients. So we had that situation. We had the primary endpoint in regards to clinical significance.

224. As a result, Defendants decided that the NEWS2 "secondary endpoint" for which CytoDyn had achieved a statistically significant value was "even more important than our primary endpoint" and would support the EUA requested of the FDA.

225. Also on August 12, 2020, Proactive Investors posted an interview of Defendant Pourhassan on its website and YouTube. During the interview, Pourhassan claimed that the Phase 2 Trial (CD10) "results have been fantastic," stating "[t]he problem we have is people don't understand . . . clinical trials, especially laymen, investors. So let me make it very clear. The results were fantastic." Pourhassan further asserted: "Now, the primary endpoint [for CD10] was clinically significant. What does that mean? . . . The difference was 90% versus 70%. If you go to a hospital" and the "rate of getting better" using leronlimab was "90% . . . versus 70% . . . everybody would take that. It's clinically significant." With respect to potential FDA approval based on CD10, Pourhassan stated: "So let's talk about best case versus worst case. . . . Best case is when [in a] pandemic, mild to moderate is [an] unmet medical need. . . . So if the FDA chooses to look at these [CD10] results," and "say, OK," they have clinical significance and "the safety was spectacular. Let's give them emergency approval. That would be fantastic." Pourhassan concluded, "I don't see how anybody in their right mind with one first grade educated person can come over here and say this was bad news about the results."

226. In other words, when the Phase 2 Trial (CD10) results did not live up to Defendants' promotional hype from the summer of 2020, they blamed the intelligence of the media and investors and deflected the negative reaction to the failure of the Phase 2 Trial (CD10) by changing their goal to match the result (i.e., the secondary endpoint is "even more important than our primary endpoint"), and requesting an EUA based on data they knew would be insufficient to achieve emergency authorization—let alone FDA approval for the sale of leronlimab to treat COVID-19. Moreover, as Defendants knew and the FDA later publicized, "***there was no observed effect of the drug on the study's primary endpoint or on any of the secondary endpoints***. . . . The CD10 trial results showed ***no clinically meaningful differences*** in

average change in 'total clinical symptom score' from baseline to Day 14 between study arms" and "***none of the secondary endpoints were met in this study***, including mortality, time to symptom resolution, and time to return to normal activity." And "[t]aken together, ***the CD10 results indicate that most study participants experienced resolution in COVID-19 symptoms regardless of whether they received leronlimab or placebo***."

227. Defendants' false, misleading, and unsubstantiated statements and promotional efforts continued after August 12, 2020. On August 17, 2020, CytoDyn announced that it had submitted the "top-line report" from the Phase 2 Trial to the FDA and "requested emergency use approval" for leronlimab to treat COVID-19 solely on that basis. In an August 19, 2020 press release, Defendants continued to spin the results of the Phase 2 Trial, relying on the fact that it had demonstrated statistical significance in one secondary endpoint to baldly assert that CytoDyn had "statistically significant efficacy findings."

228. Defendants' false, misleading, and unsubstantiated statements and promotional efforts concerning the Phase 2 Trial (CD10) results were restated and amplified by CytoDyn's paid promotional outlets. For instance, in an August 17, 2020 Proactive Investors interview, Pourhassan complained that "there is a lot of negative talk about our company and we are under attack from negative people that are very negative about CytoDyn . . . [our] stock has gone down." With regard to the CD10 trial, Pourhassan claimed "there are two outcomes. Worst case, best case. Best case is the FDA will . . . say . . . [EUA] is granted" and "worst case scenario, we do a Phase 3" trial and "hopefully have approval by the end of the year. . . . I don't know what else we could do to make sure that everybody knows that this is really strong results." Pourhassan further stated, "we . . . look forward to surpris[ing] everybody . . . wh[en] we g[e]t . . . emergency use authorization" in the U.K. or the U.S."

229. However, neither the FDA nor the U.K. MHRA granted CytoDyn emergency use authorization of leronlimab for COVID-19. Moreover, despite telling investors on August 17, 2020 that CytoDyn had formally requested an EUA for leronlimab based solely on the Phase 2

Trial (CD10) results, Defendant Pourhassan changed the narrative once again, claiming that CytoDyn had not submitted anything formally to the FDA, but rather had asked its "opinion" about whether an EUA could be granted on the strength of the Phase 2 Trial (CD10) results. The reason for Defendants' revisionist history became clear during Dr. Been's September 23, 2020 interview of Pourhassan when Pourhassan finally admitted that "the FDA sa[id], 'the results that you gave us does not qualify you for emergency-use authorization at this time.'"

230. Thereafter, a September 29, 2020 Emerging Growth report authored by "admin" claimed that leronlimab "was the first COVID-19 drug to meet their endpoint in a randomized double blind placebo controlled trial. . . . The NEWS2 score identifies patients that risk progressing. In the CD-10 trial there was a statistically significant reduction in the score over placebo (p=.023). In addition their clinical symptom score was 90% in the active arm versus 71% in placebo at day 3. Based on their patient population this was only clinically significant and with a slightly larger trial would be statistically significant."

231. In October 2020, the FDA granted only one EUA for COVID-19—to Gilead's remdesivir—for both moderate and severe/critical patients, significantly narrowing CytoDyn's path to authorization or approval in the U.S. A subsequent October 30, 2020 article authored by "ChessMaster" and posted by Zero Hedge to its website, claimed that "leronlimab's data shows a strong trend in reducing mortality, hospitalizations, and symptoms, whereas remdesivir could only manage to affect duration of hospitalization." The Zero Hedge article further speculated that "[m]uch more promising immunomodulatory therapeutics such as leronlimab are having more difficulty gaining traction and acquiring supporting clinical data due to the massive push of remdesivir." In reality, however, the failure of the Phase 2 Trial had nothing to do with remdesivir—CytoDyn simply had failed to demonstrate to the FDA that leronlimab was efficacious in mild-to-moderate COVID-19 patients.

8. With the Phase 2 Trial Missing Its Primary Endpoint, Defendants Pivot to Promoting CytoDyn's Phase 3 Trial Results, Efforts to Garner International Approval for Leronlimab and a New COVID-19 Treatment Population, "Long Haulers"

232. With its Phase 2 Trial (CD10) missing its primary endpoint, Defendants shifted their false, misleading, and unsubstantiated statements and promotional efforts to several new areas of hype with which to pump up the price of CytoDyn's common stock, including (i) CytoDyn's Phase 2b/3 Trial (CD12), (ii) non-U.S. regulatory pathways to approval/authorization, and (iii) a new potential treatment population, so-called COVID-19 long haulers.

233. On August 4, 2020, CytoDyn announced that it had received a positive Drug Safety Monitoring Committee ("DSMC") recommendation on the CD12 safety data. In an August 17, 2020 press release, Pourhassan claimed to be "in discussions with several regulatory agencies in other countries and hope to obtain emergency approval for its use" and CytoDyn expressed "hope[]" that it would "obtain emergency use approval from the MHRA in the U.K., EMA in the European Union, as well as the regulatory authorities in the Philippines." Separately, with respect to COVID-19 long-haulers, the Company announced that it had "been approached by several doctors about a clinical study of leronlimab in long-hauler COVID-19 individuals" for which "[t]he Company is preparing a Phase 3 protocol and will file it as soon as possible."

234. On August 19, 2020, CytoDyn announced that it had sent the CD10 "top-line report" to the U.K. MHRA and had "requested the regulatory pathway for Fast Track approval noting the efficacy and safety results from the Phase 2 trial." Then on August 20, 2020, CytoDyn issued another press release, this time announcing that the U.K. MHRA had "authorized the Company to enroll for its ongoing" Phase 3 Trial, following "several months of its review of CytoDyn's manufacturing processes and leronlimab's safety profile." Thereafter, the price of CytoDyn's common stock increased 25% over two trading days (August 21 and 24, 2020).

235. On August 25, 2020, CytoDyn announced in a press release that it had "reached the requisite number of enrolled patients in its Phase 3 [T]rial" such that it could "perform an interim analysis following the 28 day phase of the trial." The release quoted Defendant Pourhassan as follows: "We are eager to perform an interim analysis of the data and remain optimistic the interim results will be consistent with those experienced by patients who received leronlimab through multiple eINDs (over 60) previously authorized by the FDA. And, in the event we are successful, we are well positioned with our distribution partner to accelerate distribution of leronlimab to patients throughout the U.S."

236. Then on September 2, 2020, CytoDyn announced that the U.K. MHRA had granted the Company a meeting to discuss its request for Fast Track approval of leronlimab to treat COVID-19 based on the Phase 2 top-line report and the anecdotal eIND data. That same day, Defendants also held a conference call with investors to discuss CytoDyn's COVID-19 efforts. CytoDyn's stock price increased 38% over four consecutive trading days (September 2-4 and 8, 2020) and daily trading volume increased nearly 200% over the same period.

237. Defendants also held a conference call with investors on September 16, 2020 to further discuss CytoDyn's COVID-19 efforts. With respect to COVID-19 long-haulers, Pourhassan stated, "there is no medication for this population and we have some very exciting data generated that is absolutely powerful." Defendant Kelly likewise stated: "We believe th[e long-hauler data] is a potential game changer for CytoDyn, for CytoDyn shareholders and patients." Defendants again addressed the COVID-19 long hauler indication during a November 5, 2020 conference call. Thereafter, on November 17, 2020, CytoDyn announced that it had filed a protocol for a phase 2 clinical trial for "long-hauler" COVID-19 patients, confirming in a press release on November 23, 2020 that CytoDyn was "in full swing to . . . initiate our Phase 2 trial" for COVID-19 long-haulers "and perhaps complete enrollment in 4-6 weeks."

238. During a September 23, 2020 interview with Dr. Been, Defendant Pourhassan asserted that "the most important thing is CD12." He further explained that CytoDyn was

waiting for the results of an interim efficacy analysis by the DSMC, and hoped to obtain a recommendation that CD12 was statistically powerful enough to hit its primary endpoint. With respect to the U.K., Pourhassan told Dr. Been that the U.K. "MHRA told us that they would like [us] to go ahead and have us give them all the [eIND results] and they want to give us early access use for . . . critical patients." Per Pourhassan, the U.K. MHRA said "go ahead and apply for that [early access]." Pourhassan also claimed: "We believe we can get that [early access], because MHRA said, 'you probably could get that.'" Finally, during the interview, Pourhassan confirmed "[w]e're also looking at long-hauler . . . we got the synopsis for our protocol, and it's going to go to FDA tomorrow. And once FDA goes back and forth with us, we will have the protocol finalized most likely by the end of next week, and then we will start enrolling."

9. Defendants Redouble Their Efforts to Promote CytoDyn's Stock after the Closing Price Dips Below the $3.00 NASDAQ Uplisting Threshold

239. On September 30, 2020, CytoDyn's common stock closed below $3.00 per share for the first time since CytoDyn submitted its NASDAQ uplisting application. Although the stock price closed above $3.00 on the first few trading days in October 2020, from October 14, 2020 through December 7, 2020, CytoDyn's common stock closed under the $3.00 per share closing price threshold required for uplisting. As a result, Defendants redoubled their promotional efforts with respect to COVID-19.

240. On October 7, 2020, Defendant Pourhassan appeared on Fox Business News. During his appearance, Pourhassan claimed that "the FDA" and the U.K "MHRA" had "requested our interim analysis form our Phase [2b/]3 [Trial]." Pourhassan continued, "[w]e're very excited about the results that we're going to announce hopefully by the end of next week, because FDA has already given us 70 [eIND] . . . approval[s], more than any other company. And we had some fantastic results. . . . So because of that excitement, we think the [Phase 2b/3 Trial (CD12)] results are going to be fantastic."

241. Additionally, in response to a question regarding potential delays in approvals from the FDA, Pourhassan again touted the safety data from CytoDyn's HIV trials, "[t]he safety was so spectacular in those [1,000 patients] that we got fast [track] designation from [the U.S.] FDA, and claimed: "So end of next week is the huge day for us, because once we do our interim analysis, which is 195 patients, if we show what we showed already in the [eINDs] . . . if we have positive result, I think we should be able to get approval not just from the [FDA], but [U.K.] MHRA and other countries."

242. On October 20, 2020, CytoDyn announced that with respect to Phase 2b/3 Trial (CD12) "[t]he DSMC recommends the trial continue without modification to achieve the primary endpoint." On November 4, 6, and 9, 2020, CytoDyn's Phase 3 Trial was featured on local news outlets in Ohio, California, and Oregon. Thereafter, Defendants held a conference call with investors on November 5, 2020 to update them on CytoDyn's COVID-19 efforts.

243. On November 11, 2020, CytoDyn announced "an additional non-dilutive convertible debt offering with an institutional investor, which provides $25 million of immediately available capital." The press release quoted Pourhassan as stating that CytoDyn was "well-positioned to supply $2 billion worth of leronlimab to treat COVID-19, if emergency use authorization is approved in the next 2-4 months based on anticipated successful CD12 results."

244. Defendants' statements were reissued, amplified, and expanded upon by various promotional outlets that had received compensation from CytoDyn. For instance, on September 29, 2020, Emerging Growth issued a report on its website authored by "admin" about another bio pharmaceutical company, Galectin, in which it claimed "[t]he top repurposed COVID-19 therapeutics" is CytoDyn's leronlimab, stating, that "leronlimab is best in breed and slated for regulatory approval this year in either the US, UK, Philippines, or the European Union." Emerging Growth further claimed that "leronlimab was the first COVID-19 drug to meet [its] endpoint in a randomized double blind placebo controlled trial."

245. On October 23, 2020, Proactive Investor posted an interview of Defendant Pourhassan on its website and YouTube. During the interview, Proactive Investor asked Pourhassan about CytoDyn's declining stock price, in response to which Pourhassan stated:

> [T]he stock took off. What happened? How did it take off? We had national coverage [and positive eIND Results]. Those event[s] caused us to go from 3,500 investors to 43,000 [investors]. This stock took off and then the shorts saw the opportunity to attack us and they did. And now the stock hasn't moved. And I just got done telling the whole shareholder base that, please remember, if you going to make this decision about your stock sell or purchase, where are we now versus then ? . . . We could be the only product [for COVID-19 long haulers]. We are filing the protocol next week and we could have the enrollment finished this year in long haul. Do you want to sell shares ahead of that? And then on . . . October [26, 2020] . . . we're meeting with [the U.K.] MHRA to file BLA for final approval for HIV, which 100% we believe it's going to be fine. . . . We will follow [up] with Canada Health. And this is . . . COVID-19 and Cancer and HIV. . . . Do you have or anybody has that can match this many opportunities in this year alone? Now people think they should sell shares and that's their right. But for me, double digit [stock price]. Triple digit [stock price], if we have approval for these indications, triple digits is what I indicated. . . . I'm talking about in the very near future. So that's where we are.

246. On November 11, 2020, Proactive Investor posted another interview with Pourhassan on its website and YouTube. During the interview, Pourhassan stated, "we have manufactured successfully 1.2 million vials this year and about 3 to 4 million [for] next year. . . . When we get our emergency use authorization . . . then all we have to do is sell these [vials] at the same price that is being COVID-19 therapies are being sold. That's about $2 billion this year and about $5 billion dollars." Pourhassan further stated that if CytoDyn was able to generate this level of sales of leronlimab, CytoDyn "will give the shareholders some dividends, a couple of dollars per share dividends. We will buy back shares. We would uplist." On November 16, 2020, Proactive Investor posted to its website and YouTube a subsequent interview with Pourhassan concerning, in part, CytoDyn's COVID-19 trials.

247. On November 30, 2020, Emerging Growth posted a report on its website authored by "admin." That report claimed that "[w]hile vaccines are getting all the attention, viable therapeutics like CytoDyn's leronlimab . . . have been effectively benched by the FDA until they complete their trials," and asserted that "leronlimab is the only phase 3 therapeutic candidate in

the world expected to have a positive mortality benefit and not some feel good reduction in hospital stay which are the most recent endpoints that have been given Emergency Use Authorization (EUA)" in the U.S.

248. On December 8, 2020, Emerging Growth published on its website a report authored by contributor Chris Long. In the report, Long noted that a blogger had found a way to identify the next EUAs the FDA would grant. Based on this analysis, Long stated that the EUA for leronlimab was "expected," noting that "CYDY . . . seems to have a lot more going for it" and that the completion of COVID-19 trials "could be a major catalyst as investors flock back into this name for fear of missing a runaway freight train that may be the next drug to not only get an[] EUA but all get [sic] marketing approval." Long reiterated Pourhassan's unsubstantiated claim that COVID-19 related sales of leronlimab "could top $7 billion next year" and concluded, "CYDY is quite undervalued and given the very strong correlation of EUA approved drugs that make it to this list it should be aggressively purchased going into the shareholder update."

249. CytoDyn's stock price increased 28% over four consecutive trading days in November (November 11-13 and 16, 2020), Moreover, following the Emerging Growth report, the price and volume of CytoDyn's common stock increased 32% and 549%, respectively, over the prior trading day, finally closing above the $3.00 NASDAQ uplisting threshold for the first time since October 13, 2020.

10. As Defendants' Promotional Efforts Continue, Defendant Mulholland Sells Nearly 1.8 Million CytoDyn Shares

250. On December 15, 2020, after the close of the U.S. markets, CytoDyn announced that it had completed enrollment for its Phase 2b/3 Trial (CD12). According to the press release, the Phase 2b/3 Trial "will be analyzed in approximately 28 days with expected results to be announced shortly thereafter." Notably, the press release also announced that CytoDyn had decided to forego the second interim analysis recommended by the DSMC, purportedly in favor

of "analyz[ing] the data on 390 patients and to provide final data to" the FDA, Health Canada, the U.K.'s MHRA, and the Philippines FDA, "as soon as it is available."

251. On December 18, 2020, Emerging Growth published a report authored by Chris Long on its website titled, "Mesoblast Crashed on Poor DSMB Report Leaving CytoDyn as Sole Survivor in COVID-19 Therapeutics." According to Long's report, only Mesoblast and CytoDyn "had mortality as a primary endpoint in severe to critical COVID-19" and "CytoDyn stands as the sole survivor and will greatly benefit from the expected dip in MESO stock price because CYDY has the only therapeutic that completed a phase 3 with their primary endpoint intact and did so without increasing the trial size."

252. The Emerging Growth report further asserted that "[t]here should . . . be a corresponding reset higher" in CytoDyn's stock price "since they are the beneficiary of being the first to market," "have outlasted all their competition," and " have 3 shots on goal in this upcoming trial readout." With respect to Phase 2b/3 (CD12), the report stated, "[m]eeting just one of these endpoints is a layup for approval but it's likely that they will meet all of them," and "[a]s the only drug with a mortality benefit, they are almost guaranteed to be the new SOC." The report further asserted that "CytoDyn might also get a label expansion in moderate COVID-19 and long haulers," and "FDA approval in COVID-19 is expected early next year and they are very close to an EUA from the Philippines, the United Kingdom, and the United States." The report concluded, "[a]ll these factors combined equate to a doubling of market cap and a doubling of price. This news could drive the stock to $10.00 in the short run. . . . The best way for MESO shareholders to make their money back is to buy the best stock – CYDY."

253. CytoDyn's daily trading volume increased 356% on December 16, 2020 and its stock price increased 60% over four consecutive trading days (December 16-18 and 21, 2020). On December 17, 2020, CytoDyn's common stock closed above $4.00 per share for the first time since September 16, 2020. On December 21, CytoDyn's common stock closed at $6.00 per share, a price CytoDyn had not seen since July 20, 2020.

254. Beginning on December 17, 2020 and continuing for and additional three consecutive trading days, Mulholland exercised and sold 1,816,600 million CytoDyn shares for proceeds of $10.26 million in a matter of days. Plaintiffs traded contemporaneously with Defendant Mulholland, buying shares of CytoDyn common stock as Mulholland exercised options and sold the resulting shares at prices many times greater than the strike prices.

255. Following Defendant Mulholland's stock sales, Defendants' promotional efforts continued. On December 22, 2020, CytoDyn announced that the FDA had resumed eIND approvals following the full enrollment of CytoDyn's Phase 2b/3 Trial (CD12). On December 24, 2020, CytoDyn issued a press release announcing that the FDA had provided it guidance for an "open-label extension" tied to the Phase 2b/3 Trial (CD12), as well as specific criteria for eIND approvals, and that the Company would be submitting an open label extension protocol to the FDA on December 28, 2020. That same day, Defendant Kelly appeared on CBSN Live today to discuss the use of leronlimab to treat COVID-19. Thereafter, on December 30, 2020, CytoDyn announced that the FDA had accepted its open-label extension protocol.

256. Repeating the pattern, CytoDyn's paid promotional outlets also published articles and reports amplifying and expanding upon Defendants' statements.

257. On December 22, 2020, Zero Hedge published an article authored by ChessMaster titled, "FDA Should Restore Doctors Rights to Use Medicines That Work." ChessMaster speculated that "[t]he FDA has a serious chip on its shoulder regarding the approval process, and its mandate to protect the public by ensuring the safety, efficacy, and security of drugs" and "[t]here is clear evidence that its edicts are actually harming the American population," including with respect to leronlimab, "a very safe and efficacious HIV drug that was repurposed for COVID-19" and "demonstrated its utility in May 2020." ChessMaster further speculated that "[e]ven though it had 60 emergency INDs (eINDs) more than any drug at the time including remdesivir, the FDA closed it down citing that the high number of eIND's was

hurting enrollment in existing clinical trials" and now leronlimab "sits, two successful clinical trials later – waiting."

258. Also on December 22, 2020, Emerging Growth published a report on its website authored by Chris Long. According to the report, that morning, CytoDyn shares "screamed higher in very active trading and touched $7.00 per share to a $4.14 billion market cap." Per the report, "[i]nvestors were very enthused with the announcement that the FDA was resuming their emergency IND (eIND) approvals. . . . During April and May [2020] a number of eINDs were approved and news of their success trickled its way into major media outlets and excited the retail investors. So it's very reasonable that news of the eINDs would be a net positive for the stock ahead of the impossible stories of recovery that seemed to come about the last time eINDs were open." The report concluded, "Investors should stay peeled to the news screen and the TV screens in the coming days because it's clear that the stock price wants to move."

259. On the last trading day of 2020, December 31, CytoDyn's common stock closed at $5.39 per share, well above the $3.00 closing price threshold required by the NASDAQ exchange to uplist.

260. On January 6, 2021, Defendants held a conference call with investors. During the call, Defendant Pourhassan touted CytoDyn's stock performance (i.e., "CytoDyn's stock has now traded over $5 billion in just [the] last 12 months") and claimed that "one of our main messages was CytoDyn has its primary endpoint [in one Phase 3 HIV trial], and therefore, CytoDyn is no longer a high-risk, high-reward company, but a very low risk with high rewards [company]." Pourhassan further claimed "the past 12 months proved our case" and "CytoDyn now is in the top of the chart amongst all 11,700 OTCP companies." Pourhassan insisted CytoDyn was "enter[ing] a new chapter . . . with more powerful opportunities, more explosiveness and a future that is about to be . . . realized in 2021" including an "uplisting . . . to NASDAQ soon." With respect to uplisting, Defendant Mulholland stated: "Based upon our

recent discussion with the exchange, I believe we have a very clear path forward. We simply need to execute our plan. All of this must be supported by a stock price of greater than $4."

261. With respect to COVID-19, Pourhassan stated, "So does leronlimab have some rock solid data in regards to its efficacy in ***any*** application? The answer is yes. . . . We have . . . come a long way with COVID-19 and constantly talk about that. That's our primary focus now." Pourhassan further claimed that CytoDyn has "been approached by some countries" that have stated "they could get us . . . marketed [for COVID-19] without CD12 data. . . . [I]f that happens, we will start selling [leronlimab] right now." He also claimed that "[s]elling leronlimab without EUA is possible in other countries."

262. With respect to the Phase 2b/3 Trial (CD12), Pourhassan stated, "CD12 data is this month . . . that's what I'm very excited about. How did we do all these great things with leronlimab in [eINDs] in critical patients? Those [results] . . . speak[] volume[s]." In response to a question from a participant, Pourhassan also confirmed that CytoDyn had decided not to go forward with a Phase 3 trial in mild-to-moderate COVID-19 patients after "the primary endpoint was missed" in the Phase 2 Trial (CD10) and instead "concentrate our of our efforts on CD12."

263. On January 7, 2021, Emerging Growth issued a report authored by Chris Long. The report asserted Defendants' investor conference call the prior day, Janaury 6, 2021, may have been "one of its last" as an OTC company, as CytoDyn "could be saying hello NASDAQ, and hello EUA in the course of the next couple of weeks." With respect to the Phase 2b/3 Trial (CD12) results, the report claimed that because "the number of deaths are so low in comparison to the control populations that, statistically speaking, it is very difficult for them to fail this severe to critical trial. They are widely expected to meet their endpoint." The report also noted "a very high likelihood of approval because the Drug Safety Monitoring Committee (DSMC) let them finish their trial and agreed that the drug was meeting its endpoint of mortality."

264. With respect to the NASDAQ uplisting, the Emerging Growth report asserted, "[t]he much anticipated uplisting will happen very shortly. The company has met the $4 stock

threshold and now just needs to meet the shareholder equity requirement of $5 M. The company believes they can meet that easily." The report concluded, "CytoDyn is the number 1 volume traded stock on OTC Markets, so if they aren't worthy of an uplisting who is?"

265. On February 2, 2021, Zero Hedge posted a report authored by "Chopperone." With respect to leronlimab, the report stated, "[w]ithin a few weeks, the FDA is set to decide on a therapeutic that appears to . . . check[] all the boxes necessary to qualify as a real solution" to COVID-19. Per the report, leronlimab "has a flawless safety record" and "has had real world success" in eINDs.

266. On February 22, 2021, CytoDyn announced in a press release that the Phase 2b/3 Trial (CD12) data had "been unblinded and the results [would] be reported when the Company has concluded its ongoing discussions with regulators." The release further stated that CytoDyn expected to release Phase 2b/3 Trial (CD12) data and complete its discussions with "various regulatory agencies within 2 to 3 weeks." Despite previously issuing multiple press releases detailing every meeting with and recommendation from regulators, including Dr. Lalezari sharing the substance of CytoDyn's communications with the FDA on March 20, 2020, March 27, 2020, and April 8, 2020, and Defendant Pourhassan claiming on July 1, 2020 that "all of our FDA communication is immediately reported to the public," the February 22, 2021 press release claimed that "[d]etails of the Company's ongoing discussions with the regulatory agencies are confidential."

267. CytoDyn's stock price increased on January 27 and 29, and February 1, 2021 by 15%, 9%, and 29%, respectively, with daily trading volume increases of 142%, 20%, and 301%, respectively. Further, CytoDyn's stock price rose 17% on February 24, 2021, closing above the $4.00 threshold identified by Mulholland, at $4.72 per share.

11. The Relevant Truth Regarding Defendants' COVID-19 Scheme Is Incrementally Revealed

268. On Friday, March 5, 2021, after the close of the market, CytoDyn issued the first of three press releases describing the results of the Phase 2b/3 Trial (CD12). According to the press release issued at 5:47 pm ET, titled, "CytoDyn's Phase 3 Trial Demonstrates Safety, a 24% Reduction in Mortality and Faster Hospital Discharge for Mechanically Ventilated Critically Ill COVID-19 Patients Treated with Leronlimab" the Phase 2b/3 Trial (CD12) "demonstrated continued safety, substantial improvement in the survival rate, and faster hospital discharge in critically ill COVID-19 patients."

269. Despite the fact that the press release did not state whether the Phase 2b/3 Trial (CD12) had reached its primary endpoint, Pourhassan claimed that "there are no approved drugs to effectively address the unmet medical need for critically ill COVID-19 patients" and further speculated that "[o]ur CD12 study demonstrates leronlimab is particularly effective in treating this patient population," and asserted, "these results are the best results ever achieved for this population in a Phase 3 clinical trial." Pourhassan concluded, "[t]he Company is very excited about these results and is concurrently working with regulators here and abroad to expedite leronlimab's approval to treat COVID-19." Less than one hour later, CytoDyn issued a second press release announcing a call on Monday, March 8, 2021 to discuss the CD12 results.

270. Thereafter, on March 6, 2021, CytoDyn issued a press release entitled "CytoDyn to File Accelerated Rolling Review with MHRA and Interim Order (IO) with Health Canada for COVID-19," disclosing:

> Amongst all patients in mITT, the primary endpoint (all-cause mortality at Day 28) was not statistically significant. When age adjustment was conducted, the primary endpoint was much closer to statistically significant value. . . . With the age adjustment analysis in all other major secondary endpoints, there was consistent numerical superiority over the placebo group, with some secondary endpoints approaching statistical significance.

271. In response to Defendants' disclosures on March 5 and 6, 2021 after trading had concluded, on the next trading day, March 8, 2021, the price of CytoDyn's common stock fell by $1.14 per share—more than 28%—from a close of $4.05 on March 5, 2021, to a close at $2.91 on March 8, 2021 on heavy trading volume.

272. After the market closed on March 8, 2021, CytoDyn filed a Form 8-K with the SEC that included an executive summary of CytoDyn's most recent COVID-19 results. Thereafter, Defendants held a conference call with investors to discuss the Phase 2b/3 Trial (CD12) results. During the March 8 call, CytoDyn's Chief Scientific Officer Mahboob Rahman ("Rahman") confirmed "we did not hit the primary endpoint p-value." For his part, Defendant Pourhassan claimed that CytoDyn would "conduct [a] small 140-patient trial" to support the Phase 2b/3 Trial (CD12) data and had already had submitted a protocol for that to the FDA because the "FDA has told us" that "we have to show much better, clear numbers." He subsequently stated, "the FDA needs to have double-blinded study and that 140 patients."

273. Also on March 8, 2021, Amber Tong of Endpoint News issued an article entitled, "***CytoDyn tries to squeeze positive news out of a failed Covid-19 study – and shares take a beating***." The article stated: "CytoDyn acknowledged that leronlimab — an anti-CCR5 antibody that had already been turned away at the FDA's doorsteps once — had failed the primary endpoint of lowering all-cause mortality at Day 28, as the result was not statistically significant. At best, execs implied, they would need to collect further clinical data to be ready for regulatory reviews."

274. In response to Defendants' March 8 disclosures, on March 9, 2021, the price of CytoDyn's common stock fell by another $.56 per share—more than 19%—from a close of $2.91 on March 8, 2021 to a close of $2.35 on March 9, 2021 on heavy trading volume.

275. With the stock price declining well below both the $3.00 and $4.00 thresholds for NASDAQ uplisting in response to the disclosures concerning the Phase 2b/3 Trial (CD12) results, Defendants again redoubled their efforts to pump up the price of CytoDyn's common

stock by: (i) re-calculating and re-casting the COVID-19 trial results to appear as if leronlimab actually treated COVID-19; and (ii) issuing myriad press releases and conference call statements regarding CytoDyn's purported efforts to secure authorization for leronlimab use to treat COVID-19 in the U.S., the U.K., and Canada, among other countries.

276. For instance, in the first March 5, 2021 press release, CytoDyn confirmed that the CD12 data had been provided to the FDA, the U.K.'s MHRA, and Health Canada and that CytoDyn was "in discussions with each to determine the best path forward for approval of leronlimab for treatment of COVID-19." Twenty-four hours later, on Saturday, March 6, 2021, CytoDyn issued a third press release titled "CytoDyn to File Accelerated Rolling Review with MHRA and Interim Order (IO) with Health Canada for COVID-19" announcing "multiple regulatory pathways for approval of leronlimab . . . in the U.S., U.K. and Canada." With respect to Canada, CytoDyn went so far as to state that "the Health Canada Interim Order (IO) could allow the Company to ***sell*** leronlimab in Canada, while additional critical COVID-19 patients are enrollled," but, of course, CytoDyn had only "initiated the process to submit" as opposed to actually submitting "an IO with Health Canada."

277. During a March 8, 2021 call with investors, Pourhassan continued to assert that the results were "fantastic" and "very strong" and claimed that "three regulatory agenc[ies], including [the] U.S. FDA are working with us and have suggested the final path to approval of leronlimab for COVID-19 in multiple countries, including [the] USA." Pourhassan further stated, "[w]e expect to sell leronlimab for COVID-19 for many years to come in [the] U.S. and abroad." Moreover, according to Pourhassan, "the most important message for all of our shareholders in today's call is that we believe CD12 demonstrated that leronlimab works" and "this was proven in CD12." Pourhassan further claimed that a number of doctors "all believe[] the results are very strong to warrant conditional EUA while we generate more data." As described in the March 8 Endpoint News article, "CytoDyn zoomed in on a subgroup that accounted for 62 out of 384 patients enrolled in the CD12 trial and declared a survival benefit" and "massag[ed] the data."

278. Zero Hedge also posted a report on March 8, 2021, titled "Successful Top Line Phase 3 Readout Shows Leronlimab Saves 1 in 4 Patients – Will the FDA Take Action?" Authored by "ChessMaster," the report stated, "[t]his weekend CytoDyn stunned the world with a top line readout that reduced COVID-19 mortality by 24%, and if age adjusted reduced it by 40%," calling the clinical trial a "homerun for the planet." The report further claimed, "[u]nfortunately for CytoDyn, a data anomaly is potentially delaying what would normally result in an almost automatic . . . [EUA] with the FDA. . . . The data is actually so good that in spite of [the data anomaly] they were able to pull out some amazing clinical trial results that demonstrate a tremendous mortality benefit." The report continued, "a statistical anomaly should not condemn thousands of people to their deaths."

279. Moreover, the Zero Hedge report blamed the DSMC for the Phase 2b/3 Trial (CD12)'s results, but speculated that the DSMC's "blunder" in not recommending that CytoDyn change the primary endpoint of that trial, "could be undone by the interim chief of the FDA," Janet Woodcock. According to Zero Hedge, "[i]t will also be very hypocritical if Woodcock fails to approve the drug" given her prior statements including, "would you be willing to die to give a p-value?" The report also suggested that "there could be an incredible outcry for an immediate EUA," noting that "it is reasonable to suspect that [clinicians] will be knocking down the FDA's door demanding an EUA approval" and "if an EUA isn't granted almost immediately Janet Woodcock can almost be assured of a congressional investigation as the clinicians write their congressmen."

280. Defendants also had begun repackaging the CD12 trial data such that it would appear as if leronlimab was actually safe and efficacious in the relevant patient population. For example, the March 6, 2021 Press Release explained that "an 'age adjustment' analysis was performed" which appeared to generate statistically significant results for two sub-populations. The "'age adjustment' analysis did not change the results for "all patients in MITT"; for those

patients CytoDyn finally admitted that "the primary endpoint . . . was not statistically significant."

281. Then on March 30, 2021, CytoDyn issued "further results from its CD12 trial." According to the Company, "[u]pon further statistical analysis," "it was revealed that when leronlimab was added to standard of care ("SoC"), leronlimab decreased mortality at 14 days by" a statistically significant amount. Based on that same "further statistical analysis," CytoDyn also reported that leronlimab "was associated with a 400% improvement in the ranking on the 7-point ordinal scale at 14 days," which was also statistically significant." Commenting on this "further statistical analysis, Pourhassan stated, "[w]e will expediently submit an update with the above 14-day benefit to the U.S. FDA, Health Canada, and MHRA and will work closely with regulators in other countries. The Company believes this new information bolsters the case for immediate use of leronlimab for critically ill patients. Furthermore, we believe these results suggest that to see maximum effect of leronlimab at day 28, we must use three to four doses of leronlimab and not just two doses, as was the case with CD12 (day zero and day 7 only)."

282. That same day, Emerging Growth issued a report authored by "admin" titled, "CytoDyn Stuns FDA with 400% Improvement in 14 Day Mortality." The "report" described the March 30, 2021 press release numbers as "stunning." More broadly, as to the "trial results," first reported on March 8, 2021, the Emerging Growth report claimed that leronlimab "is superior to any existing therapy," "[t]he 28 day data set represents the strongest clinical data ever achieved in any randomized controlled clinical trial around the world," "[t]he magnitude of these results is unprecedented anywhere in the world," and "[t]his data is a clean win for CytoDyn and the world." Accordingly, the Emerging Growth report claimed that instead of an EUA, the trial results "supports a more aggressive approach of ***approval***" and demonstrate that "leronlimab . . . is . . . likely to receive FDA ***approval*** in the short run."

283. As for the leronlimab EUA, linking to YouTube videos, the Emerging Growth report claimed that "[t]he genie is out of the bottle and doctors and clinicians are rising up on

social media pleading with the FDA for an EUA" and that CytoDyn's "trial results put tremendous pressure on the FDA to issue an EUA." The Emerging Growth report further claimed that the FDA's failure to issue an EUA for leronlimab, "put[] many lives at risk" and could lead to "a highly publicized congressional inquiry about the FDA's inaction on a safe and effective drug" where the FDA "would be held accountable." The Emerging Growth report concluded that "these clinical trial results may seal their [CytoDyn short-sellers'] fate and finally force a cover. If that happens the stock could be trading north of $20.00 per share."

284. In addition to refocusing their promotional efforts on non-U.S. regulatory approval of leronlimab, Defendants also suggested that approval of leronlimab was imminent. For example, in an April 5, 2021 press release announcing another convertible debt offering, Defendant Pourhassan explained that "[t]his infusion of capital will help ensure we have sufficient quantities of leronlimab available upon any potential approvals for COVID-19 treatment." CytoDyn announced that it had raised another $25 million in a second convertible debt offering three weeks later, on April 23, 2021, for a total of $50 million in just three weeks. Commenting on the second debt offering in a same day Proactive Interview, Pourhassan claimed that the Phase 2b/3 Trial (CD12) was "not a failure."

285. CytoDyn's stock price on March 30, 2021, April 1 and 5, 2021 (consecutive trading days) of 32%, 18%, and 25%, respectively, with increases in daily trading volume of 231% on March 30, 2021 and 199% on April 5, 2021.

286. On or before April 30, 2021, a video titled "leronlimab, the little drug that could" was loaded onto YouTube. The video opens with a voiceover by Dr. John Bream, an E.R. physician, reading a quote from FDA Acting Commissioner, Woodcock: "people say they want placebo-controlled trials, but I always ask them . . . would you be willing to die for a p-value?," Bream responded: "Evidently that number is close to 100,000 because we have concluded the trial of leronlimab in December [2020] and at least 100,000 Americans have died since then." After walking through a mash-up of U.S. and Philippine news clips with voice-overs from

unidentified people claiming that leronlimab is safe and has worked to treat COVID-19 patients, the video concludes with another unidentified voiceover stating: "I am calling on the FDA to provide an emergency use authorization for leronlimab immediately." Currently, the video only is available through an archived webpage. On April 30, 2021, CytoDyn's common stock price rose 13% with a 77% increase in daily trading volume.

287. Then, on May 17, 2021, the FDA took the unprecedented step of publicly issuing a statement regarding an unapproved drug. Per the FDA's "Statement on Leronlimab," "[a]lthough FDA generally cannot disclose confidential information about unapproved products, . . . given the significant public interest in leronlimab, it is important to provide summary information about the status of the CytoDyn development program. . . . ***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***."

288. With respect to the Company's two COVID-19 trials, the FDA's Statement on Leronlimab clarified the actual results, removing the gloss and spin that Defendants had been adding these results for months. With respect to the Phase 2 Trial (CD10), the FDA stated that "***there was no observed effect of the drug on the study's primary endpoint or on any of the secondary endpoints***. . . . The CD10 trial results showed ***no clinically meaningful differences*** in average change in 'total clinical symptom score' from baseline to Day 14 between study arms" and "***none of the secondary endpoints were met in this study***, including mortality, time to symptom resolution, and time to return to normal activity." The FDA further stated, "[t]aken together, ***the CD10 results indicate that most study participants experienced resolution in COVID-19 symptoms regardless of whether they received leronlimab or placebo***."

289. Moreover, according to the FDA, the Phase 2b/3 Trial (CD12) "***also failed to find any effect of the drug on the primary study endpoint***, with no difference seen in mortality (20.5% in the leronlimab treatment group and 21.6% in the placebo treatment group); or on any

of the secondary endpoints, for example, with no difference on the average length of hospitalization (21.4 days in both the leronlimab and the placebo treatment groups)."

290. With respect to Defendants' efforts to recast, recalculate, or otherwise reanalyze the Phase 2b/3 Trial (CD12) results, the FDA stated, "[i]f the analyses of the primary and secondary endpoints do not support conclusions of the medicine's benefit, then FDA considers subgroup analyses to be exploratory, meaning" that they "***do not support reliable conclusions about the medicine's benefit***." This is because, according to the FDA, "[f]ocusing 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."

291. More specifically, the FDA concluded, "[s]ubgroup 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***."

292. Responding to the FDA's Statement on Leronlimab, Adam Feuerstein of *STAT+* stated, "[t]he [FDA] . . . took the extraordinary step of issuing a lengthy statement on an unapproved drug, rejecting claims made by the troubled drug maker CytoDyn about its failed antibody treatment for Covid-19. CytoDyn's CEO, Nader Pourhassan, has repeatedly touted the potential of the drug, leronlimab, on conference calls, YouTube videos, and in press releases, saying the treatment was shown to have saved lives in clinical trials. The FDA said it had determined otherwise."

293. In response to the FDA's Statement on Leronlimab, on May 17, 2021, the price of CytoDyn's common stock fell by $.76 per share—more than 27%—from a close of $2.80 on May 14, 2021, to a close at $2.04 on May 17, 2021 on heavy volume.

12. Post-Class Period Events

294. On May 24, 2021, the SEC sent CytoDyn's then-Chief Financial Officer, Antonio Migliarese, a letter regarding the Company's upcoming Form 10-K. In the letter, which was posted to the EDGAR website, the SEC wrote:

> We note statements in your proposed disclosure for Item 1 and Note 4 that you believe leronlimab is safe and effective, as well as language implying the existence of 'clinical data that supports its safety and efficacy.' As safety and efficacy determinations are within the authority of the U.S. Food and Drug Administration and comparable regulatory bodies, ***please revise your proposed disclosure to remove language that states or implies that you believe leronlimab is safe and effective or that leronlimab is likely to be found safe and effective.***

295. On July 30, 2021, Defendants disclosed that CytoDyn was being investigated by both the SEC and the DOJ. Specifically, in its Form 10-K for FY20, CytoDyn revealed that it had received "subpoenas" from the SEC "requesting documents and information" and CytoDyn and "and certain of its executives have received subpoenas" from the DOJ seeking "testimony and/or records" concerning CytoDyn's "public statements regarding the use of leronlimab as a potential treatment for COVID-19 and related communications with the FDA, investors, and others and trading in the securities of CytoDyn."

296. On December 4, 2021 Alex Berenson posted an article on Substack claiming that his recent FDA FOIA request yielded an April 30, 2021 e-mail from the FDA's Director of Social Media, Brad Kimberly regarding the April 30, 2021 YouTube video, "Leronlimab, the Little Drug that Could." Based on the screen shot of the document provided by the author of the article, it appears that the FDA sought to have the video removed from YouTube on or around April 30, 2021 because it believed that it was "misleading when it comes to COVID-19." More specifically, the screen shot of Kimberly's email states: "This video is misleading. The drug identified [leronlimab] ***has not been identified by the US FDA as safe and effective against***

COVID-19 and is not authorized or approved for such use. It also conflates the Fillipino FDA and US FDA by misusing the USFDA logo and ***implying that it is planning to evaluate the drug for an EUA, which isn't true***. Overall, the video is very problematic when it comes to COVID misinformation."

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

297. During the Class Period, Defendants made a series of materially false and misleading statements and omitted material facts regarding: (i) the HIV BLA; (ii) the efficacy and safety of leronlimab for COVID-19; and (iii) the results of the Phase 2 Trial (CD10) and Phase 2b/3 Trial (CD12).

A. The HIV BLA

298. On April 9, 2020, CytoDyn filed a Form 10-Q for the fiscal quarter ended February 29, 2020. The Form 10-Q was signed and certified by Defendant Pourhassan. In the Form 10-Q, CytoDyn stated:

> The Company's inventory ***as of February 29, 2020*** and May 31, 2019 ***was $15,895,589*** and $0, respectively. ***Inventory as of February 29, 2020 consisted*** solely of specialized raw material purchased for use in the commercial manufacturing of pre-launch inventories of Vyrologix to support the Company's expected approval of the product as a combination therapy for HIV patients in the United States. The Company believes that ***all material uncertainties related to the ultimate regulatory approval of Vyrologix for commercial sale have been significantly reduced based on positive data from Phase III clinical trial results, information gathered from pre-filing meetings with the Food and Drug Administration for the Biologics License Application ("BLA"), and the Company's anticipated filing of the BLA with the FDA targeted for the end of April 2020.***
>
> ***As of the date of this filing the Company does not have any evidence that regulatory approval will be denied***. However, the BLA for HIV combination therapy has not been filed.

299. On April 27, 2020 CytoDyn issued a press release entitled, "CytoDyn Submits Completed Biologics License Application (BLA) to the FDA for Leronlimab as a Combination Therapy for Highly Treatment Experience HIV Patients." CytoDyn stated in the press release

that "***CytoDyn completed the filing of its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients***."

300. In the same release, Pourhassan stated, "***[w]ith the BLA filing for a combination therapy now complete***, we are continuing our efforts on commercialization-readiness, as well as advancing leronlimab in the other important therapeutic areas of COVID-19, cancer and immunology. The BLA filing is a monumental achievement for our Company . . . ."

301. On April 27, 2020, CytoDyn issued a second press release entitled, "CytoDyn Announces Vyrologix as Proprietary Name for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients in the United States" stating, "***CytoDyn completed the filing of its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experience HIV patients***."

302. On April 27, 2020, during a CytoDyn Investor Community Call, Pourhassan stated: (i) "The first update is ***the BLA submission, which is a historical achievement for CytoDyn***. . . ."; (ii) "The good news is, ***CytoDyn just filed the full BLA*** last night . . . ."; (iii) "So in short, ladies and gentlemen, ***the BLA is submitted*** . . ."; and (iv) "***The BLA got filed***."

303. On April 29, 2020, CytoDyn issued a press release entitled, "CytoDyn's Drs. Pourhassan and Patterson to Present Live at Wall Street Reporter's Event to Discuss Paper Recently Submitted for Publication and Positive Results of eIND COVID-19 Patients," in which it stated that it had "***completed the filing of its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients***." On April 30, 2020, CytoDyn issued a press release entitled, "CytoDyn Reports Strong Results from eIND COVID-19 Patients Treated with Leronlimab; Majority of Patients Have Demonstrated Remarkable Recoveries," in which it stated the same language.

304. On May 4, 2020, CytoDyn issued a press release entitled, "FDA Approves 54 Emergency INDs for Leronlimab Treatment of Coronavirus – CytoDyn Requests Compassionate Use from FDA for COVID-19 Patients Not Eligible for Participation in Two

Ongoing Clinical Trials in U.S. – CytoDyn Targets Enrollment Completion for its 75 Patient, Phase 2 Trial by End of May," in which it stated "[the BLA] ***will be considered completed after the clinical datasets are submitted on May 11, 2020***." (This disclosure constitutes both a material false and misleading statement, as Defendants misrepresented that the HIV BLA would be complete in short order and minimized the issues that called for the supplemental submission of data, and, as explained herein, the first partial corrective disclosure of Defendants' fraud, as it revealed for the first time some indication of shortcomings in the HIV BLA—albeit wrapped in reassurances that the submission would be complete on May 11, 2020.)

305. On May 6, 2020, CytoDyn issued a press release entitled, "Manuscript Describes How CytoDyn's Leronlimab Disrupts CCL5/RANTES-CCR5 Pathway, Thereby Restoring Immune Homeostasis, Reducing Plasma Viral Load, Reversing Hyper Immune Activation and Inflammation in Critical COVID-19 Patients," in which it stated, "[w]e would like to provide an update that ***the Biologics License Application (BLA) for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients will be considered completed after the clinical datasets are submitted on May 11, 2020. The clinical datasets are updated to address FDA comments for mock datasets from March 12 and March 20, 2020***."

306. On May 8, 2020, CytoDyn issued a press release entitled, "CytoDyn Clarifies Status of Biologics License Application," in which it stated: (i) "***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***"; (ii) "***The Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients to the FDA on April 27, 2020***"; and (iii) "***CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients, and plans to submit additional datasets needed to complete the BLA on May 11, 2020***."

307. On May 13, 2020, CytoDyn issued a press release entitled, "CytoDyn Completed Submission of All Remaining Parts of Biologics License Application ("BLA") on May 11, 2020," in which it stated that it "***confirmed***" that "***on May 11, 2020, it submitted all remaining parts of the Company's Biologics License Application ('BLA') for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients to the [FDA].*** Pursuant to FDA guidelines, ***CytoDyn informed the FDA it had submitted a complete BLA for rolling review***." CytoDyn further stated in the same press release that "***[t]he Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients to the FDA on April 27, 2020 and submitted the additional FDA requested clinical datasets on May 11, 2020***." It further stated in the same press release that "***CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients, and submitted additional FDA requested clinical datasets on May 11, 2020***."

308. On May 15, 2020, CytoDyn issued a press release entitled, "CytoDyn to Offer No-Cost Exploratory Laboratory Testing for Childhood Inflammatory Disease Associated with COVID-19," in which it stated that ***"[t]he Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients with the FDA on April 27, 2020, and submitted additional FDA requested clinical datasets on May 11, 2020***" and "***CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients, and submitted additional FDA requested clinical datasets on May 11, 2020***." CytoDyn made ***identical statements*** to the market in press releases issued on (and titled): (i) May 18, 2020, ("CytoDyn to Prepare a Phase 3 Protocol to Submit to the FDA for a Three-Arm Comparative and Combination Trial of Leronlimab and Remdesivir"); (ii) May 19, 2020, ("CytoDyn and the Mexican National Institutes of Health Participate in a Collaborative Study of Leronlimab for the Treatment of Severe/Critical COVID-19 Population"); (iii) June 1, 2020, ("CytoDyn Files Request With FDA

for Priority Review of BLA for First Approval"); (iv) June 8, 2020, ("CytoDyn Receives BLA Acknowledgment Letter From the FDA"); (v) June 11, 2020, ("CytoDyn Reached Its Enrollment Target for Phase 2 COVID-19 Trial for Mild to Moderate Indication – Primary End Point Announcement Is Next"); (vi) June 11, 2020, ("CytoDyn Initiates Phase 2 Clinical Trial with Leronlimab for Treatment of Nash"); (vii) June 29, 2020, ("CytoDyn and NIH of Mexico Complete Memorandum of Understanding to Conduct Small Covid-19 Phase 3 Trial for Severe and Critically Ill Patients"); (viii) July 2, 2020, ("CytoDyn Releases Mechanism of Action Animation for Leronlimab in Immuno-Oncology"); (ix) July 3, 2020, ("CytoDyn Announces Execution of Exclusive Agreement with American Regent for Distribution and Supply of Leronlimab for Treatment of COVID-19 in United States"); (x) July 6, 2020, ("CytoDyn Announces Execution of Exclusive Agreement with American Regent for Distribution and Supply of Leronlimab for Treatment of COVID-19 in United States"); and (xi) July 7, 2020, ("CytoDyn's Leronlimab Prevents Transmission of SHIV in Macaque Study").

309. On May 15, 2020, during a Proactive Investors interview, Pourhassan stated, the "***BLA [was] already submitted***."

310. On May 20, 2020, during a Proactive Investors interview, Pourhassan stated that he believed the HIV BLA was a "***complete package***."

311. On May 26, 2020, during a Proactive Investors Interview, Pourhassan stated that the HIV BLA was "***submitted with rolling review***."

312. On July 4, 2020, in statements made during an interview entitled, "Leronlimab Discussion with Dr. Been," Pourhassan stated: "***We said in, I believe April 27th, that we submitted the full BLA. FDA immediately said 'no, we don't agree'. And we immediately set [sic] to the public that it is not completed. It's going to be completed in a few more days, and it was***." (Some emphasis in original.)

313. On July 8, 2020, CytoDyn issued two press releases in which it stated: "***CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for***

highly treatment experienced HIV patients, and submitted additional FDA requested clinical datasets on May 11, 2020."

314. The statements set forth in ¶ 298 were materially false and misleading when made because Defendants knew or were deliberately reckless in not knowing that CytoDyn lacked various types of data that were critical to the HIV BLA, and was not capable of submitting a complete HIV BLA in the time frame specified. For example, as set forth in detail in Section V.A and VII.A-B, CytoDyn did not possess data, information, or analyses the FDA had expressly stated were required to be submitted in the HIV BLA, including: (i) complete bioanlytical reports; (ii) full validation data for all PPQ lots analyzed; (iii) complete CCR5 receptor occupancy data for 350 mg, 525 mg, and 700 mg doses; (iv) analyses of Anti-Drug Antibodies (ADA) or any assessment of association between ADA and virlogic failure; and (v) multiple reports needed for the FDA to permit a substantive review. Therefore, Defendants' statements about the anticipated submission date of the HIV BLA in April 2020 and asserting that the Company did not have evidence that the HIV BLA would be denied, and the Company's counting of its leronlimab supplies as an inventory asset, lacked a reasonable basis in fact.

315. In addition, Defendants' statements set forth above in ¶¶ 299-313 asserting that the BLA was, e.g., "complete" and/or "completed," "filed," and/or "submitted" were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in Sections V and VII, at the time Defendants issued these statements, they knowingly or recklessly misrepresented, concealed, and/or failed to disclose that:

a. The CEO of Amarex, CytoDyn's CRO that was conducting the overall development of the HIV BLA, including managing multiple data analyses and essential projects related thereto, specifically warned Pourhassan prior to April 14, 2020 that the HIV BLA was incomplete.

b. Nevertheless, on April 14, 2020, Pourhassan ordered that the HIV BLA be submitted in April 2020 regardless of known shortcomings. In an April 14, 2020

e-mail, Pourhassan directed the BLA be filed in April 2020 "***no matter what portion of whatever it is that we are short***." As Amarex's CEO has stated in a sworn declaration, "Pourhassan directed Amarex to file the BLA prematurely, knowing it was incomplete, lacking in appropriate content and not ready for submission."

c. CytoDyn (and thus the HIV BLA) lacked data that the FDA had expressly told CytoDyn in the June 2018 Pre-BLA Meeting must be included in a complete application "at the time of the BLA submission," including "complete bioanalytical reports" and "full validation data from all PPQ lots."

d. CytoDyn (and thus the HIV BLA) lacked data that the FDA had expressly told CytoDyn in the December 14, 2018 Teleconference must be included in a complete application, including "data from studies conducted with the drug in the device," and "information on the manufacturer of the syringe and needles."

e. CytoDyn (and thus the HIV BLA) lacked data that the FDA had expressly told CytoDyn in the January 2019 MPPRC Meeting and in its December 16, 2019 correspondence to CytoDyn must be included in a complete application, including "CCR5 receptor occupancy data" for three separate doses sizes. CytoDyn had only representative data for two sizes.

f. CytoDyn (and thus the HIV BLA) lacked data that the FDA had expressly told CytoDyn must be included in a complete application, including "a Pop PK analysis to support the selection of a higher dose [700 mg, based on the dose-finding study in the monotherapy study (CD03)] than the dose evalutated in the pivotal trial (CD02)" (alteration in original).

g. CytoDyn (and thus the HIV BLA) lacked data that the FDA had expressly told CytoDyn in its January 22, 2019 correspondence must be included in a complete

application, including "analyses of Anti Drug Antibodies (ADA) or any assessment of any association between ADA and virologic failure."

h. CytoDyn (and thus the HIV BLA) lacked data that the FDA had expressly told CytoDyn in its November 11, 2019 correspondence must be included in a complete application, including "an integrated assessment of efficacy," and adequate efficacy comparisons as between the dose group and randomized arms of the study.

i. Finally, CytoDyn (and thus the HIV BLA) lacked data that the FDA had expressly told CytoDyn in its December 16, 2019 correspondence must be included in a complete application, including: (i) "the information and analyses needed to permit FDA reviewers (clinical, statistical, clinical virology and clinical pharmacology) to perform a substantive review of the proposed dose"; (ii) "an integrated assessment that incorporates detailed summaries reflecting data from the participants randomized to receive 350 mg, 525mg, and 700mg in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02"; and (iii) "multiple reports that are needed to permit a substantive review."

316. By electing to speak publicly about CytoDyn's purported complete HIV BLA submission and datasets and/or information that the FDA requested—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the HIV BLA submission and there was no reasonable basis to misrepresent that the HIV BLA submission was properly filed or that CytoDyn submitted the datasets and/or information that the FDA actually requested.

B. COVID-19

1. Statements Concerning Safety and Efficacy of Leronlimab

317. On May 1, 2020, Defendant Pourhassan and Dr. Patterson participated in Wall Street Reporter's Next Super Stock livestream. During the May 1, 2020 livestream, Dr. Patterson stated:

> And then ***to be able to publish with statistical significance the findings encoded that underlie why Leronlimab will work*** before the statistical significance comes from the trials is --is a source of great excitement ***because there's two levels of clinical significance.*** Obviously, we have to let the FDA do their thing. We are absolutely on board with that and doing it the right way with the FDA. But at the end of the day, we—***we're looking at the data on how the drug works on COVID and saying, hey, the drug is doing what it's supposed to be doing and that's statistically significant.*** So we--we have great, great confidence that because it's been embedded into the trial design that we're going to have a positive outcome, at least in my opinion.

318. On June 2, 2020, Defendant Pourhassan and Dr. Lalezari participated in Wall Street Reporter's Next Super Stock livestream. During the June 2, 2020 livestream, Pourhassan stated: "As we said, you know, the unblinding we will have for CD10, very much likely on June 15th, and of the June, ***the primary endpoint will be read out to the world, and we hope to shock the world with the very beautiful results***."

319. On the same livestream, in response to a question from an audience member about where leronlimab would rank "in comparison to all time successful drugs," Dr. Lalezari stated:

> I'm not sure I want to speculate too much on the future, but I--I will say that if we look at the rest of the COVID-19 landscape, there's no other drug that is showing this kind of antiviral effect. … So, yes, ***it is utterly amazing how well and that effect is being seen in 100 percent of patients***. So, you know, I don't—I'm wary of the future … As I said, there's no precedent for this, that a new drug—you would know a drug would work from emergency IND data before you even understood how it was working or even before you had randomized clinical studies. So I think Nader is doing a great job to try and match reality with leronlimab, with what is happening. But the—certainly the potential is that this is groundbreaking and the world has never seen anything like it, and in my heart of hearts, I think this drug's a home run. And in my heart of hearts, I wish we'd had it approved six weeks ago and maybe could have saved the first hundred thousand lives, but yes, this story is going to have a huge impact. And ***my biggest concern would be making sure there's enough drugs to treat everybody in the world who's going to need it. That's at the end of the day. That's going to be the biggest challenge.***"

320. On the same livestream, in response to a question as to what data existed to show that "patients improved as a result of leronlimab and not just a spontaneous resolution of the virus, Lalezari stated: "The results are even more astonishing because as a group, these patients were so ill and so terminal . . . . But ***it doesn't seem to me to be a huge stretch to take the data in patients who are terminal and then see in the [e]IND results evidence of the same clinical benefit***."

321. Defendants' statements set forth above in ¶¶ 317-20 were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19 and that, per the FDA, "the data currently available do not support the clinical benefit of leronlimab for the treatment of COVID-19." By electing to speak publicly about the safety and efficacy of leronlimab to treat COVID-19 and thereby putting these subjects into play Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the safety and efficacy of leronlimab to treat COVID-19 and there was no reasonable basis to misrepresent that then-existing data supported the clincial benefit of leronlimab for the treatment of COVID-19.

2. Statements Concerning the Phase 2 Trial (CD10) Results

322. On August 12, 2020, Defendants held a conference call with investors. During the call, Defendant Pourhassan stated:

> In regards to our study, many questions have come. Did we meet our primary endpoint? Meeting your primary endpoint — that means you have to have a clinically significant value, and if it's the value is much better in the drug versus placebo, then that becomes a statistically significant. If it's not statistically significant, but clinically significant, then your Phase 3 will do the same thing as Phase 2, but with a higher number of patients.
>
> So, we had that situation. ***We had the primary endpoint in regards to clinical significance***.
>
> ***
>
> But, something happened to these trials. Something fantastic we have discovered. We discovered that there is a secondary endpoint that we believe is even more

> important than our primary endpoint, and ***we have achieved a statistically significant value for that, which is the so-called NEWS2***. NEWS2, which is the updated version of NEWS. N-E-W-S, which is National Early Warning Score. NEWS2 assess the degree of illness that points out to any need for critical care intervention. This means we lowered this risk of having this combination of seven parameters that constitute the NEWS score, and we have done it by [1]50% better than placebo.
>
> ***
>
> And these seven parameters are very important parameters. Just look at them. Their respiratory rate, oxygen saturation, supplemental oxygen, temperature, systolic blood pressure, heart rate, and level of consciousness. So, these are very important parameters that are used to give you a score. Our score was 50% in leronlimab versus 20% in placebo. ***That was statistically significant***. That means the risk of critical-care intervention due to use of leronlimab was reduced by two-and-half times. And our safety has been very amazing.

323. During the same call, Defendant Kelly stated: "We just showed statistical significance in a randomized, double-blinded, placebo-controlled study from a tool that helps identify which patients will deteriorate and require prompt critical care intervention [NEWS2]. I think that's remarkable."

324. Additionally, in response to the following question, "I . . . read the statistical significance on Day 3, in terms of the clinical response. But at Day 10 and 14, there was no difference between the drug and placebo, or there was a difference, but it did not reach statistical significance?" Defendant Pourhassan stated: So day seven and fourteen for symptom score in the pre-protocol, it was not significant. So we didn't even talk about it. ***We only talk about the one that had clinical significance – three days, which we thought it was the most important part***."

325. On August 17, 2020, CytoDyn issued a press release titled, "CytoDyn Submits its Top-Line Report from its Phase 2 COVID-19 Trial to the U.S. FDA and Requests Emergency Use Approval." The press release quoted Defendant Pourhassan as follows:

> We believe ***the statistically significant data of NEWS2 findings***, along with impressive safety results (less SAEs or AEs with leronlimab vs. placebo), from our Phase 2 trial set forth in the Top-line Report ***provides compelling data in support of leronlimab's use to fight COVID-19***. We are in discussions with several regulatory agencies in other countries and hope to obtain emergency approval for its use.

326. On August 19, 2020, CytoDyn issued a press release titled, "CytoDyn Requests 'Fast Track Approval' for COVID-19 Patients from U.K.'s Regulatory Agency MHRA based on its Top-line Report Showing Statistically Significant Endpoint, NEWS2 (p <0.023) and Notably Safety Results," where Defendant Pourhassan again touted the Phase 2 Trial (CD10) "***statistically significant efficacy findings***."

327. On August 20, 2020, CytoDyn issued a press release titled, "After Several Months of Providing Requested Information About Manufacturing and Safety of Leronlimab, U.K.'s MHRA Accepts CytoDyn's Request to Enroll in its Current Phase 3 Trial for COVID-19 Patients with Severe-to-Critical Symptoms," where Defendant Pourhassan likewise touted the Phase 2 Trial (CD10) as having "***strong efficacy and safety data***."

328. Defendants' statements set forth above in ¶¶ 322-27 were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19. More specifically, Defendants' statements asserting that the Phase 2 Trial (CD10) had showed "clinical significance" with respect to its primary endpoint and "statistically significant" with respect to the NEWS2 secondary endpoint and otherwise provided "compelling data" for leronlimab's use to treat COVID-19 were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, per the FDA: (i) "the data currently available," including Phase 2 Trial (CD10), "do not support the clinical benefit of leronlimab for the treatment of COVID-19"; (ii) "there was no observed effect of the drug on the study's primary endpoint or on any of the secondary endpoints"; (iii) "[t]he [Phase 2] CD10 trial results showed no clinically meaningful differences in average change in 'total clinical symptom score' from baseline to Day 14 between study arms"; (iv)"none of the secondary endpoints were met in this study, including mortality, time to symptom resolution, and time to return to normal activity"; and (v) "the [Phase 2] CD10

results indicate that most study participants experienced resolution in COVID-19 symptoms regardless of whether they received leronlimab or placebo." Moreover, by electing to speak publicly about the safety and efficacy of leronlimab to treat COVID-19 and the results of the Phase 2 Trial (CD10) and thereby putting these subjects into play Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the safety and efficacy of leronlimab to treat COVID-19 and the Phase 2 Trial (CD10) results and there was no reasonable basis to misrepresent that then-existing data supported the clincial benefit of leronlimab for the treatment of COVID-19.

329. On March 5, 2021, CytoDyn issued a press release titled, "CytoDyn's Phase 3 Trial Demonstrates Safety, a 24% Reduction in Mortality and Faster Hospital Discharge for Mechanically Ventilated Critically Ill COVID-19 Patients Treated with Leronlimab" ("March 5, 2021 Press Release"). In the press release, CytoDyn disclosed that the Phase 2b/3 Trial (CD12) "***demonstrated continued safety, substantial improvement in the survival rate, and faster hospital discharge in critically ill COVID-19 patients***."

330. The March 5, 2021 Press Release further stated that: (i) "[t]here was a 24% reduction in all-cause mortality (primary endpoint of the study) in the leronlimab versus placebo"; (ii) "[t]he average length of hospital stay was reduced by 6 days for patients who received leronlimab with 'commonly used COVID-19 treatments,' also referred to as 'Standard of Care' or 'SoC,' compared to placebo patients who received SoC only, with a statistically significant p-value of 0.005"; and (iii) "patients who received leronlimab demonstrated an improved probability of 'discharged alive' at Day 28 (28% versus 11%), a 166% better rate than the placebo group."

331. The March 5, 2021 Press Release quoted Defendant Pourhassan as follows:

> Our [Phase 2b/3] CD12 study demonstrates leronlimab is particularly effective in treating [critically ill COVID-19 patients]. We believe these results are the best results ever achieved for this population in a Phase 3 clinical trial . . . leronlimab demonstrated a reduction of 24% in mortality compared to the SoC treated group, which is 12 times better in reducing all-cause mortality for critically ill COVID-19 patients. The Company is very excited about these results and is concurrently

> working with regulators here and abroad to expedite leronlimab's approval to treat COVID-19.

332. On March 6, 2021, CytoDyn issued a press release titled, "CytoDyn to File Accelerated Rolling Review with MHRA and Interim Order (IO) with Health Canada for COVID-19" ("March 6, 2021 Press Release") "announc[ing] . . . multiple regulatory pathways for approval of leronlimab as a treatment for critical COVID-19 patients in the U.S. . . ." In the March 6, 2021 Press Release, CytoDyn stated that it was "pleased to show strong data for critically ill COVID-19 patients."

333. The March 6, 2021 Press Release further stated:

> [A]n "age adjustment" analysis was performed and consequently, the updated results from the primary endpoint analysis are as follows:
>
> 1) Statistically significant results (p-value = 0.0319) reported for the primary endpoint (all-cause mortality at Day 28) in participants receiving leronlimab + "commonly used COVID-19 treatments" compared to participants who received "commonly used COVID-19 treatments" alone in the placebo group in the overall modified intent-to-treat ("mITT") population.
>
> 2) Statistically significant results (p-value = 0.0552) reported for the primary endpoint (all-cause mortality at Day 28) among participants who received dexamethasone as the prior or concomitant standard of care treatment ("SoC") for COVID-19, compared to patients who received dexamethasone (without leronlimab) as SoC therapy in the overall mITT population.
>
> 3) Amongst all patients in mITT, the primary endpoint (all-cause mortality at Day 28) was not statistically significant. When age adjustment was conducted, the primary endpoint was much closer to statistically significant value. Of note, the reduction of mortality in this population of 65 years and younger leronlimab arm had more than 30% less mortality than placebo and 9% less mortality in participants over 65.
>
> With the age adjustment analysis in all other major secondary endpoints, there was consistent numerical superiority over the placebo group, with some secondary endpoints approaching statistical significance.

334. CytoDyn reissued the March 5, 2021 Press Release and the March 6, 2021 Press Release on March 8, 2021.

335. Also on March 8, 2021, CytoDyn issued a press release entitled, "CytoDyn to Release CD12 Trial Detailed Results via Form 8-K After Investment Community Webcast,

Monday, March 8" ("March 8, 2021 Press Release"). The March 8, 2021 Press Release included the statements set forth above in ¶¶ 330 and 333.

336. Defendants' statements set forth above in ¶¶ 329-35 were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19.

337. More specifically, Defendants' statements asserting the Phase 2b/3 Trial (CD12) "show[s] strong data" and "demonstrates" that leronlimab is "particularly effective in treating critically-ill" COVID-19 patients, and that Defendants had "multiple regulatory pathways for approval of leronlimab as a treatment for critical COVID-19 patients in the U.S." and were using the Phase 2b/3 Trial (CD12) to "expedite leronlimab approval" were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, per the FDA: (i) the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug on the primary study endpoint, with no difference seen in mortality (20.5% in the leronlimab treatment group and 21.6% in the placebo treatment group); or on any of the secondary endpoints, for example, with no difference on the average length of hospitalization (21.4 days in both the leronlimab and the placebo treatment groups)"; (ii) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analyses of the primary and secondary endpoints do not support conclusions of the medicine's benefit"; (iii) "[s]ubgroup analyses have well-established limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study population"; (iv) "[f]ocusing 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"; and (v) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met

statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

338. Additionally, Defendants' statements that Phase 2b/3 Trial (CD12) "demonstrated . . . substantial improvement in the survival rate" of critically ill patients and a "24% reduction in all-cause mortality rate (the primary endpoint of the study)" in critically ill patients, and the "age adjusted analysis" and "updated results from the primary endpoint analysis" for three different subgroups were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew but did not disclose that the Phase 2b/3Trial (CD12) "failed to find any effect of the drug on the primary study endpoint," and, also per the FDA: (i) the analysis of "subgroup[s]"—here, critically-ill patients, patients taking leronlimab + standard of care, all mITT[9] patients, and mITT patients taking leronlimab + dexamethasone—"do not support reliable conclusions about the medicine's benefit" where, as here, "the analys[i]s of the primary . . . endpoint[] do[es] not support conclusions of the medicine's benefit"; and (ii) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

339. Likewise, Defendants' statements that the Phase 2b/3 Trial "demonstrated an improved probability of 'discharged alive' at Day 28" and a "statistically significant" reduction in the "average length of hospital stay . . . by 6 days" in the subgroup of patients that took leronlimab + the standard of care were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew but did not disclose that the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug . . . on any of the secondary

[9] "mITT" refers Modified Intention-to-Treat. The "Intention-to-Treat" principle requires that all participants in a randomized study be included in the final analysis and analyzed according to their assigned treatment group regardless of what happened during the patient's participation in the study. There is no clear definition of "mITT" as it can vary from trial to trial, but effectively, mITT indicates that some participants were excluded when the results were unblinded.

endpoints," and per the FDA: (i) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analys[i]s of the . . . secondary endpoints do not support conclusions of the medicine's benefit"; (ii) "[s]ubgroup analyses have well-established limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study population"; and (iii) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons." Moreover, by electing to speak publicly about the safety and efficacy of leronlimab to treat COVID-19 and the results of the Phase 2b/3 Trial (CD12) and thereby putting these subjects into play Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the safety and efficacy of leronlimab to treat COVID-19 and the Phase 2b/3 Trial (CD12) results and there was no reasonable basis to misrepresent that then-existing data supported the clincial benefit of leronlimab for the treatment of COVID-19.

340. Additionally, on March 8, 2021, Defendants held a conference call with investors. During the call, Defendant Pourhassan stated that CD12 "showed [a] statistically significant secondary endpoint."

341. Speaking for CytoDyn, Rahman also stated: "if you look at the data . . . even in the overall population, you will see consistently in essentially all different endpoints, you see a benefit, maybe numerical, but you see a benefit consistently." Rahman continued:

> we . . . prespecified the critically ill patients as one of the subpopulations that we will test our primary and secondary endpoint. And if you look at those prespecified analysis, you will see that this – the mortality was reduced by 24% in this critically ill patient population, which was defined as ordinal scale 2, which means intubated – either just intubated or on ECMO. These patients, 24% mortality was reduced.
>
> Then if you look at the time to recovery or discharge from hospitals, our hospital stay in this patient population, you actually see a statistically significant difference, 6 days less in this patient population.
>
> And another secondary endpoint, which is called discharge alive through day 28, and in here, we see a pretty wide difference between the patient who received

> leronlimab, 28%, versus patients who only received standard of care, 11%, a 166% better rate than placebo.
>
> So with these results in this critically ill patient population, we think that regulatory authorities will take a very close look and see if there is a potential for saving lives under the conditions that we are in right now, with essentially no medication having an impact in the mortality and benefit in the critically ill population.

342. Additionally, during the same call Defendant Pourhassan stated: "Critically ill population, we've shown relative reduction in mortality of 24%. In regard to the whole population, we talk about 309 patients severe and critical. What happened when they took were commonly used drugs and leronlimab versus placebo, and we talk about 233 patients that took dexamethasone with leronlimab versus dexamethasone and placebo."

343. Defendant Pourhassan and Rahman had the following colloquy in response to questions posed by Arian Colachis ("Colachis"), CytoDyn's VP, General Counsel & Secretary during the same call:

> COLACHIS: . . . ClinicalTrials.gov named all-cause mortality as the primary endpoint. Why report the 24% reduction in all-cause mortality without a p-value?
>
> POURHASSAN: We discussed that. We put the p-value for primary endpoint. Critical yield was another primary endpoint.
>
> COLACHIS: The press release does not support a p-value for shortened time to recovery but nowhere is shortened time to recovery listed as an endpoint at ClinicalTrials.gov. Do you want a future trial protocol to include this as an endpoint?
>
> ***
>
> RAHMAN: Maybe in the ClinicalTrials.gov, it is listed as hospital stay -- length of hospital stay, which is the same as essentially shortened time to recovery. We just made it more understandable in terms of lingo but it's the same. And that is one of the secondary endpoint, and that is the one that was statistically significant in the critically ill population.

344. In response to the following question posed by Colachis, "What is the difference between overall mortality and probability of being discharged alive?", Defendant Pourhassan and Rahman stated:

> POURHASSAN: So discharged alive was ordinal scale of 2. Everybody was scored between 1 to 7, 1 being dead to being on invasive mechanical ventilator, intubated in ICU. And 7 was released from hospital with no problem. 6 was released from hospital with some minor problems. So those patients who walk out with OS 2 and they received a score of 6 to 7, and that's what we evaluated at the time of discharge because 6 and 7 means discharged.
>
> ***
>
> RAHMAN: So to explain it simply, overall mortality is patients who died. And discharged alive not only takes into account whether you're alive but also takes into account that you are well enough to leave the hospital. So it's a combination of being alive and well enough to leave the hospital. So you may be alive, but you're not in a condition to leave the hospital by day 28 because that's also a benefit. And as I said before, in this endpoint, you see that the patients who received leronlimab, 28% of them were able to leave the hospital by day 28, whereas only 11% of the standard of care. So--so yes, so it takes into account death as well as how well you are feeling if you're alive.

345. Further, on March 8, 2021, CytoDyn filed with the SEC as Exhibit 99.1 to a Form 8-K the "EXECUTIVE SUMMARY CD12_COVID-19 STUDY 04-MAR-2021" ("March 8, 2021 Form 8-K"). Defendant Mulholland signed the March 8, 2021 Form 8-K.

346. With respect to the Phase 2b/3 Trial (CD12) results, the March 8, 2021 Form 8-K stated:

> **Survival benefit**: A favorable, **statistically significant results (p value 0.0319)** reported for the primary endpoint (all-cause mortality at Day 28) in participants receiving leronlimab + "commonly used COVID-19 treatments" compared to participants who received "commonly used COVID-19 treatments" alone in the placebo group in the **overall mITT population**.
>
> Similar **statistically significant results (p value 0.0552)** reported for the primary endpoint (all-cause mortality at Day 28) among participants who received dexamethasone as the prior or concomitant standard of care treatment for COVID-19, compared to patients who received dexamethasone (without leronlimab) as standard of care therapy in the **overall mITT population**.
>
> ***
>
> **Shortened time to recovery**: The average length of hospital stay was lower in leronlimab group compared to placebo/SoC group in the critically ill population with a statistically significant p value of 0.0050 using the Rank-ANCOVA model.
>
> ***

> Leronlimab **improved the probability of "discharged alive"** at Day 28 in the overall mITT population as well as in the critically ill population with the results trending towards statistical significance.

(Emphases in original.)

347. The March 8, 2021 Form 8-K also stated: "The safety analysis of leronlimab in COVID-19 patients was found consistent with the established extensive safety profile with over 1000 patients treated across other multiple studies and indications."

348. The March 8, 2021 Form 8-K further stated: "The potential benefit of adding leronlimab to SoC was consistently seen in the critically ill patient population by virtue of numerically better results for all pre specified evaluated clinical endpoints."

349. Defendants' statements set forth above in ¶¶ 340-48 were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19. More specifically, Defendants' statements that leronlimab's "safety profile" was "established," the Phase 2b/3 Trial (CD12) "consistently" showed "a benefit" " in essentially all endpoints" "even in the overall population" as well as in "critically ill patient[s]" taking leronlimab with "SoC" "for all pre-specified evaluated clinical endpoints" were materially false and misleading, omitted material facts, and lacked a reasonable basis because Defendants knew or were deliberately reckless in not knowing that, per the FDA: (i) the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug on the primary study endpoint, with no difference seen in mortality (20.5% in the leronlimab treatment group and 21.6% in the placebo treatment group); or on any of the secondary endpoints, for example, with no difference on the average length of hospitalization (21.4 days in both the leronlimab and the placebo treatment groups)"; (ii) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analyses of the primary and second endpoints do not support conclusions of the medicine's benefit"; (iii) "[s]ubgroup analyses have well-established

limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study population"; (iv) "[f]ocusing 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"; and (v) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

350. Additionally, Defendants' statements that Phase 2b/3 Trial (CD12) demonstrated a "[s]urvival benefit" including "favorable, statistically significant results . . . reported for the primary endpoint" in two subgroups (leronlimab + SoC and leronlimab + dexamethasone) and a "relative reduction in mortality of 24%" in a "pre-specified" critically ill patient subgroup were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, also per the FDA: (i) the Phase 2b/3Trial (CD12) "failed to find any effect of the drug on the primary study endpoint," and, per the FDA; (ii) the analysis of "subgroup[s]"—here, critically-ill patients, patients taking leronlimab + SoC, all mITT patients, and mITT patients taking leronlimab + dexamethasone—"do not support reliable conclusions about the medicine's benefit" where, as here, "the analys[i]s of the primary . . . endpoint[] do[es] not support conclusions of the medicine's benefit"; and (iii) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons."

351. Likewise, Defendants' statements that the Phase 2b/3 Trial demonstrated "shortened time" for recovery, including a "statistically significant" reduction in "average length of hospital stay" in critically ill patient subgroup, "[l]eronlimab improved the probability of 'discharged alive'" in two subgroups (overall mITT population and critically ill patients), and CD12 "showed a statistically significant endpoint" were materially false and misleading, omitted

material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, per the FDA: (i) the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug . . . on any of the secondary endpoints"; (ii) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analys[i]s of the . . . secondary endpoints do not support conclusions of the medicine's benefit"; (iii) "[s]ubgroup analyses have well-established limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study population"; and (iv) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons." Moreover, by electing to speak publicly about the safety and efficacy of leronlimab to treat COVID-19 and the results of the Phase 2b/3 Trial (CD12) and thereby putting these subjects into play Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the safety and efficacy of leronlimab to treat COVID-19 and the Phase 2b/3 Trial (CD12) results and there was no reasonable basis to misrepresent that then-existing data supported the clincial benefit of leronlimab for the treatment of COVID-19.

352. On March 30, 2021, CytoDyn issued a press release titled, "CytoDyn's Leronlimab Decreased Mortality at 14 Days by 82% With Statistically Significant P-Value of 0.0233 Amongst Critically Ill COVID-19 Patients." The press release stated:

> Upon further statistical analysis of the critically ill population (hospitalized patients receiving invasive mechanical ventilation (IMV) or ECMO), it was revealed that when leronlimab was added to standard of care ("SoC"), leronlimab decreased mortality at 14 days by 82% (p=.0233, N=62). Patients who received leronlimab were over five times more likely to be alive at day 14 than those who received SoC only.
>
> Furthermore, leronlimab administration was associated with a 400% improvement in the ranking on the 7-point ordinal scale at 14 days when given in conjunction with SoC (p=.021, N=62) in the critically ill population, which provides direct evidence of tangible patient improvement.

353. The press release further stated:

> This analysis builds upon the previously released information from the Company's mITT analysis of CD12 showing:

- A clear benefit when leronlimab was used in addition to "commonly used COVID-19 treatments," in the primary endpoint of all-cause mortality at day 28 with an absolute risk reduction of death of 6.5% and a relative risk reduction of death of 28.1% (N=309, p=.0319).

- A clear benefit when leronlimab was used in combination with dexamethasone, in the primary endpoint of all-cause mortality at day 28 with an absolute risk reduction of death of 5.7% and a relative risk reduction of 26.0% (N=233, p=.0552).

- Length in hospital stay decreased by 5.5 days in the critically ill population (N=62, p=.005).

- A clear trend toward mortality benefit at day 28 with an absolute risk reduction of death of 20.9% and a relative risk reduction of death of 73% when leronlimab was used in addition to "commonly used COVID-19 treatments" in the critically ill population with an age ≤ 65 years old.

- A clear trend toward mortality benefit at day 28 with an absolute risk reduction of death of 16.3% and a relative risk reduction of death of 73.5% when leronlimab was used in addition to dexamethasone in the critically ill population ≤ 65 years old.

354. The press release also quoted Defendant Pourhassan as follows: "The Company believes this new information bolsters the case for immediate use of leronlimab for critically ill patients. Furthermore, we believe these results suggest that to see maximum effect of leronlimab at day 28, we must use three to four doses of leronlimab and not just two doses, as was the case with CD12 (day zero and day 7 only)."

355. Defendants' statements set forth above in ¶¶ 352-54 were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that the FDA had not determined that leronlimab was safe or efficacious in any indication, including HIV, cancer, and COVID-19. More specifically, Defendants' statements that (i) "further statistical analysis" of the critically ill subgroup demonstrated a statistically significant reduction of mortality at 14 days and "direct evidence of tangible patient improvement" on the ordinal scale, (ii) the new "analysis" showed a "clear" mortality "benefit" or a "clear trend toward [a] mortality benefit" in various subgroups, and (iii) the purportedly "new information" in the March 30, 2021 Press Release "bolster[ed] the

case for immediate use of leronlimab for critically ill patients" were materially false and misleading, omitted material facts, and lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, per the FDA: (i) the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug on the primary study endpoint, with no difference seen in mortality (20.5% in the leronlimab treatment group and 21.6% in the placebo treatment group); or on any of the secondary endpoints, for example, with no difference on the average length of hospitalization (21.4 days in both the leronlimab and the placebo treatment groups)"; (ii) the Phase 2b/3 Trial (CD12) subgroup analyses "do not support reliable conclusions about the medicine's benefit" where, as here, "the analyses of the primary and secondary endpoints do not support conclusions of the medicine's benefit"; (iii) "[s]ubgroup analyses have well-established limitations, especially in the context of a clinical trial [such as this one] that has failed to show a benefit in the overall study population"; (iv) "[f]ocusing 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"; and (v) "[n]one of th[e subgroup] analyses" for Phase 2b/3 Trial (CD12) "met statistical significance when using established and reliable analytical methods that correct for multiple comparisons." Moreover, by electing to speak publicly about the safety and efficacy of leronlimab to treat COVID-19 and the results of the Phase 2b/3 Trial (CD12) and thereby putting these subjects into play Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the safety and efficacy of leronlimab to treat COVID-19 and the Phase 2b/3 Trial (CD12) results and there was no reasonable basis to misrepresent that then-existing data supported the clincial benefit of leronlimab for the treatment of COVID-19.

VI. LOSS CAUSATION

356. During the Class Period, shares of CytoDyn's publicly traded common stock traded over the counter, and the market for those shares was open, well-developed, highly liquid

and efficient. Indeed, CytoDyn's common stock traded at high volumes during the Class Period, averaging well over 10 million shares traded per day, with daily volumes exceeding 30 million shares more than fifteen times, and 100 million shares at least twice.

357. Throughout the Class Period, Defendants' materially false and misleading statements and omissions alleged above in Section [V] created and/or maintained artificial inflation in the price of CytoDyn common stock. Defendants also engaged in a scheme to deceive the market, and in a course of conduct that operated as a fraud or deceit on Class Period purchasers of CytoDyn common stock, by failing to disclose and misrepresenting the adverse facts detailed in this complaint. When Defendants' prior misrepresentations and omissions of material fact and fraudulent scheme or course of conduct that operated as a fraud or deceit became apparent to the market, the price of CytoDyn common stock fell sharply in direct response, as the prior artificial inflation created and/or maintained by Defendants' materially false or misleading statements and actions in furtherance of their fraudulent scheme dissipated. As a result of their purchases of CytoDyn common stock during the Class Period, Plaintiffs and other Class members suffered economic loss, or damages, under the federal securities laws.

358. The artificial inflation created and/or maintained by Defendants' alleged misrepresentations and omissions and fraudulent scheme was removed from the price of CytoDyn common stock in direct response to information made public in the corrective disclosures alleged in this Section. Through those corrective disclosures, facts that related to and corrected Defendants' prior misrepresentations and omissions and fraudulent scheme were revealed.

A. Partial Corrective Disclosure Regarding Defendants' Fraudulent Misrepresentations Concerning the Leronlimab BLA: May 4, 2020

359. On May 4, 2020, CytoDyn issued a press release entitled, "FDA Approves 54 Emergency INDs for Leronlimab Treatment of Coronavirus – CytoDyn Requests Compassionate Use from FDA for COVID-19 Patients Not Eligible for Participation in Two

Ongoing Clinical Trials in U.S. – CytoDyn Targets Enrollment Completion for its 75 Patient, Phase 2 Trial by End of May," ("May 4, 2020 Press Release"). The release referred to the HIV BLA that CytoDyn had submitted to the FDA in April 2020. In the May 4, 2020 Press Release, CytoDyn noted that it would be submitting certain additional data to the FDA, and stated an "update that the Biologics License Application (BLA for Leronlimab as a Combination Therapy for Highy Treatment Experienced HIV Patients will be considered completed after the clinical datasets are submitted on May 11, 2020." This was the first, incremental revelation of the fact that the BLA suffered from material shortcomings, and of Defendants' fraud.

360. As a direct result of Defendants' disclosure, the price of CytoDyn common stock fell $0.43 per share, over 13%, from a close of $3.20 on the prior trading day, May 1, 2020, to a close of $2.77 on May 4, 2020, on volume of over 12,490,000 shares.

361. The sharp decline in CytoDyn's stock price was the direct result of Defendants' fraud regarding the BLA being partially revealed to the market. The material, negative news about the incomplete BLA was the only material, negative news released at the time, and caused the price decline. The timing and magnitude of the decline negates any inference that it, or the related loss suffered by Plaintiffs and the Class, were caused by changed market conditions, macroeconomic or industry factors, or Company-specific factors unrelated to Defendants' fraudulent conduct.

B. Corrective Disclosure Regarding Defendants' Fraudulent Misrepresentations Concerning the Leronlimab BLA: July 13, 2020

362. On July 13, 2020, CytoDyn issued a press release entitled, "Update on HIV-BLA-PDUFA: FDA requested more information to complete substantive review. No additional trials required. CytoDyn plans to submit the requested information and will ask for a Type A meeting with the FDA per agency's suggestion" ("July 13, 2020 Press Release"). In the July 13, 2020 Press Release, CytoDyn stated: "The FDA has informed the Company its BLA does not contain certain information needed to complete a substantive review and therefore, the FDA will not file

the BLA at this time." The release referred to the BLA for an HIV-related indication that CytoDyn had submitted to the FDA in April 2020.

363. Later the same day, CytoDyn held a Conference Call ("July 13, 2020 Conference Call"). During the July 13, 2020 Conference Call, Pourhassan disclosed a bombshell to investors, admitting for the first time that CytoDyn had received an RTF from the FDA in response to its BLA submission. Pourhassan stated that the purpose of "[t]oday's call is to explain the letter from the FDA requesting information about our BLA filing that has received a Refuse-to-File and did not get the PDUFA date."

364. As a direct result of Defendants' disclosures, on July 13, 2020, the price of CytoDyn's common stock fell by $1.03 per share—nearly 22%—from a close of $4.73 on July 10, 2020 to a close at $3.70 on July 13, 2020 on abnormally high trading volume of 21,148,900 shares.

365. The sharp market price decline was widely understood by market watchers to relate to the negative news that the FDA had given CytoDyn and RTF. For example, on July 13, 2020, Amber Tong of *Endpoints News* issued an article entitled, "CytoDyn shares slammed as BLA filing for leronlimab in HIV hits a wall," and stated:

> In a press release issued in early June announcing a BLA acknowledgment letter from the FDA, CytoDyn CEO Nader Pourhassan said he is hopeful about getting a PDUFA date for its lead drug, leronlimab, on July 10.
>
> Instead, they received a refuse-to-file letter today.
>
> ***
>
> July is shaping up to be an important month, Pourhassan promised, and the RTF is nothing to worry about.
>
> "We are 100% committed and confident we can provide the necessary information to the FDA as soon as possible," he said in a statement. "No additional trials will be required and all the information the FDA has requested is obtainable."
>
> Investors are less confident. Shares $CYDY fell 21.99% to $3.69.

366. Industry observers also noted this major, negative piece of Company news, which could delay any chance of approval for an HIV-related BLA for leronlimab by many months, if not years, given the need to remedy the (undisclosed) issues and resubmit a new BLA. It also caused some to question whether Defendants' prior statements to investors about the BLA had been misleading. For example, on July 13, 2020, Adam Feuerstein of *STAT+* issued an article entitled, "FDA refuses application for HIV drug from CytoDyn, raising more questions about its credibility," which stated:

> The Food and Drug Administration refused to accept an application seeking the approval of a drug to treat HIV from CytoDyn — a setback that could delay a decision for months, if not years.
>
> The so-called Refuse-to-File letter, issued by the FDA against CytoDyn's drug called leronlimab, is also the most damning evidence yet that CEO Nader Pourhassan and other company executives might be misleading investors.
>
> The price of CytoDyn shares have jumped tenfold this year based on unsubstantiated claims made by Pourhassan that leronlimab could become a blockbuster HIV drug, cure 22 different types of cancer, or save the lives of patients with Covid-19. In May, Pourhassan sold CytoDyn shares worth $12 million.
>
> CytoDyn was seeking the approval of leronlimab, an injectable medicine, for use in combination with already approved antiretroviral pills, to treat patients with HIV that had grown resistant to standard therapy.
>
> After years of delays, CytoDyn said it had submitted an application for leronlimab to the FDA in late April, only to admit in May that the submission was incomplete because unspecified "mock datasets" had been sent to FDA instead of "clinical datasets."
>
> In June, CytoDyn issued another statement claiming the leronlimab application was finally complete. Then came Monday's announcement admitting that the FDA refused to accept the leronlimab filing. Without offering specifics, CytoDyn said the leronlimab application "does not contain certain information needed to complete a substantive review." The FDA is also requesting "additional information."
>
> CytoDyn offered no timeline for when it will meet with the FDA to discuss the Refuse-to-File letter, or when it will be able to resubmit the leronlimab application.

367. Further, during the July 13, 2020 Conference Call, an analyst named Robert Smith asked, "[i]n the interest of being clear and transparent, why not just share the FDA letter

with us, with the shareholders?" Pourhassan responded, "[s]haring the FDA letter with a forth [sic] public. No? No company that I know give to their shareholders – the FDA's communication to the public." The specific substance and contents of the RTF were not revealed until the FDA document was disclosed in the course of litigation between Amarex and CytoDyn in 2021. Nevertheless, on July 13, 2020, investors learned critical new information—that the BLA had suffered a major setback for reasons that could prompt an RTF (i.e., fundamental deficiencies), resulting in an indefinite delay for any leronlimab HIV BLA approval. This highly-value relevant negative news surprised investors and corrected Defendants' materially misleading statements regarding the supposedly completed BLA.

368. The drastic and sudden decline in CytoDyn's stock price was the direct result of Defendants' fraud regarding the BLA being revealed to the market. The timing and magnitude of the decline negates any inference that it, or the related loss suffered by Plaintiffs and the Class, were caused by changed market conditions, macroeconomic or industry factors, or Company-specific factors unrelated to Defendants' fraudulent conduct.

C. Partial Corrective Disclosures Regarding Defendants' Fraudulent Misstatements and Scheme Concerning Leronlimab and COVID-19: March 5, March 6, and March 8, 2021 Disclosures

369. On Friday March 5, 2021, after the close of the market, and Saturday, March 6, 2021, CytoDyn issued press releases entitled, "CytoDyn's Phase 3 Trial Demonstrates Safety, a 24% Reduction in Mortality and Faster Hospital Discharge for Mechanically Ventilated Critically Ill COVID-19 Patients Treated with Leronlimab," and "CytoDyn to File Accelerated Rolling Review with MHRA and Interim Order (IO) with Health Canada for COVID-19," respectively. The releases purported to address the results of leronlimab's Phase 2b/3 Trial (CD12) for a COVID-19 indication. The March 5 press release did not mention whether the study's primary endpoint had been reached, while the March 6 press release admitted severely negative news for CytoDyn: that the primary endpoint "was not statistically significant." Specifically, the March 6, 2021 press release, disclosed:

> Amongst all patients in mITT, the primary endpoint (all-cause mortality at Day 28) was not statistically significant. When age adjustment was conducted, the primary endpoint was much closer to statistically significant value. Of note, the reduction of mortality in this population of 65 years and younger leronlimab arm had more than 30% less mortality than placebo and 9% less mortality in participants over 65.
>
> With the age adjustment analysis in all other major secondary endpoints, there was consistent numerical superiority over the placebo group, with some secondary endpoints approaching statistical significance.

370. As a direct result of Defendants' disclosures, on the next trading day, March 8, 2021, the price of CytoDyn's common stock fell by $1.14 per share—over 28%—from a close of $4.05 on March 5, 2021 to a close of $2.91 on March 8, 2021 on high trading volume of 21,383,800 shares.

371. Market observers tracking the news reacted to CytoDyn's latest misstep. For example, on March 7, 2021, Adam Feuerstein of *STAT+* published an article with the title, "***CytoDyn's wild weekend of data-mining study results ends in failure for its Covid treatment***." The article stated, "[r]esults from a late-stage clinical trial released late Friday by the drug maker CytoDyn showed its experimental antibody leronlimab failed to improve the survival of patients hospitalized with severe, life-threatening cases of Covid-19" and "[i]nstead of acknowledging the negative outcome of the Phase 3 clinical trial, however, CytoDyn issued two statements over the weekend claiming results spun from a small slice of patients were positive and warranted approval as a treatment for Covid-19." Further, "CytoDyn has now completed two unsuccessful clinical trials of leronlimab in patients with Covid-19. With all the negative data, there is no reason to expect the FDA or any other regulatory agency to authorize the drug's use. CytoDyn's assertions to the contrary are a smokescreen aimed at confusing inexperienced investors who don't know any better."

372. Then, after the market closed on March 8, 2021, CytoDyn filed a Form 8-K and held an investor conference call addressing the Phase 2b/3 Trial (CD12) results. On the call, CytoDyn confirmed that it had "not hit the primary endpoint p-value." Pourhassan announced

plans to conduct a new trial involving 140 patients. In other words, Defendants disclosed that they were scrambling for a way to salvage a failed Phase 2b/3 Trial (CD12), with no clear plan in sight.

373. As a direct result of Defendants' disclosures, on March 9, 2021, the price of CytoDyn's common stock fell by an additional $0.56 per share—over 19%—from a close of $2.91 on March 8, 2021 to a close of $2.35 on March 9, 2021 on abnormally high trading volume.

374. Market observers tracking the news attributed the sharp stock price decline and investor losses to the disclosure of the failed Phase 2b/3 Trial (CD12). For example, on March 8, 2021, Amber Tong of *Endpoints News* published an article with the title, "***CytoDyn tries to squeeze positive news out of a failed Covid-19 study—and shares take a beating***." The article stated:

> CytoDyn really, really wanted to put its best foot forward.
>
> So much so that, after sitting on unblinded Phase IIb/III data on leronlimab in Covid-19 for two weeks pending regulatory discussions, the biotech issued six press releases over the weekend, each offering a little more information or refining what was previously disclosed.
>
> In one of them, CytoDyn acknowledged that leronlimab — an anti-CCR5 antibody that had already been turned away at the FDA's doorsteps once — had failed the primary endpoint of lowering all-cause mortality at Day 28, as the result was not statistically significant. At best, execs implied, they would need to collect further clinical data to be ready for regulatory reviews.
>
> Shares $CYDY slid 20.99% to $3.20 once the stock market opened on Monday.
>
> That's not what they chose to highlight, though.
>
> Rather, CytoDyn zoomed in on a subgroup that accounted for 62 out of 384 patients enrolled in the CD12 trial and declared a survival benefit. Whereas the trial involved severe to critically ill patients, the company found that mechanically ventilated critically ill patients saw a 24% reduction in all cause-mortality between the leronlimab and placebo arms, without breaking down the number of deaths in either group.
>
> ***
>
> Further massaging the data, execs pointed out that there were more over-65 patients taking leronlimab than placebo — leading them to conduct a post hoc

> "age adjustment" analysis and deduce "(s)tatistically significant results (p-value = 0.0319)" for the primary endpoint "in participants receiving leronlimab + 'commonly used COVID-19 treatments' compared to participants who received 'commonly used COVID-19 treatments' alone in the placebo group in the overall modified intent-to-treat ('mITT') population."

375. On March 8, 2021, *Seeking Alpha* issued an article entitled "CytoDyn's leronlimab fails to improve survival in COVID-19 patients" and stated, "[e]ven after applying the age adjustment, the study missed its primary endpoint and all other major secondary endpoints among all patients in the modified intent-to-treat population."

376. The drastic and sudden decline in CytoDyn's stock price on March 8 and 9, 2021 was the direct result of Defendants' fraud regarding the Phase 2b/3 Trial (CD12) being partially revealed to the market. The timing and magnitude of the decline negates any inference that it, or the related loss suffered by Plaintiffs and the Class, were caused by changed market conditions, macroeconomic or industry factors, or Company-specific factors unrelated to Defendants' fraudulent conduct.

D. Final Corrective Disclosure Regarding Defendants' Fraudulent Misstatements and Scheme Concerning Leronlimab and COVID-19: May 17, 2021 Disclosure

377. The final corrective disclosure in this action occurred on May 17, 2021. On that date, the FDA formally issued a "Statement on Leronlimab." Specifically, the FDA stated:

> FDA recognizes the substantial public interest in medicines that are being studied for the prevention or treatment of COVID-19, especially those medicines that may provide a benefit to patients with the most severe forms of disease that can result in respiratory failure and death. Leronlimab, a monoclonal antibody investigational drug under development by CytoDyn, Inc. (CytoDyn), is one of the potential medicines that has been studied to determine whether it is safe and effective in treating patients with COVID-19, including those with severe outcomes from COVID-19.
>
> CytoDyn has conducted two separate clinical trials investigating leronlimab for the treatment of COVID-19. A smaller trial, titled CD10, which included 86 patients, studied leronlimab's effect on mild-to-moderate COVID-19 disease. A larger trial, titled CD12, which included 394 patients, studied leronlimab's effect on severe symptoms of respiratory illness associated with COVID-19. CytoDyn has communicated information to the public about the results of these trials. Although FDA generally cannot disclose confidential information about unapproved products, we have concluded that given the significant public interest in leronlimab, it is important to provide summary information about the status of

the CytoDyn development program.

First, we underscore the significance of a well-designed clinical trial when evaluating whether a medicine is safe and effective for a particular use. Well-designed trials have specific objectives, referred to as "endpoints", that are documented (i.e., pre-specified) in the study protocol before the initiation of the investigation. Data obtained from the clinical trial are later analyzed using pre-specified statistical methodologies. If the analyses of the primary and secondary endpoints do not support conclusions of the medicine's benefit, then FDA considers subgroup analyses to be exploratory, meaning they may inform the design of future trials, but do not support reliable conclusions about the medicine's benefit. 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. In the smaller study that CytoDyn conducted in patients with mild-to-moderate COVID-19 disease (CD10), there was no observed effect of the drug on the study's primary endpoint or on any of the secondary endpoints. The primary endpoint for the CD10 trial relied on a measure of participants' COVID-19 symptoms called a "total clinical symptom score", which was assigned based on the severity of each participant's fever, muscle aches, shortness of breath, and cough. This score ranged from 0 (no symptoms) to 12 (all 4 symptoms present and severe). The CD10 trial results showed no clinically meaningful differences in average change in "total clinical symptom score" from baseline to Day 14 between study arms (-3.5 in the leronlimab group versus -3.4 in the placebo group). Additionally, none of the secondary endpoints were met in this study, including mortality, time to symptom resolution, and time to return to normal activity. Taken together, the CD10 results indicate that most study participants experienced resolution in COVID-19 symptoms regardless of whether they received leronlimab or placebo.

The larger trial that CytoDyn conducted in patients with severe COVID-19 disease (CD12) also failed to find any effect of the drug on the primary study endpoint, with no difference seen in mortality (20.5% in the leronlimab treatment group and 21.6% in the placebo treatment group); or on any of the secondary endpoints, for example, with no difference on the average length of hospitalization (21.4 days in both the leronlimab and the placebo treatment groups).

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. However, as noted above, such analyses may inform the design of future clinical trials investigating leronlimab for the treatment of COVID-19.
>
> If CytoDyn plans further studies of leronlimab to determine whether the drug can provide clinical benefit to individuals with COVID-19, FDA will continue to provide advice to the company on their development program.

378. In effect, the FDA publicly refuted and rejected Defendants' repeated claims, implicit and explicit, to the market that leronlimab had shown meaningfully positive clinical trial results in terms of safety and efficacy as a potential treatment for COVID-19. This was a remarkable, devastating rebuke by the regulator.

379. In direct response to the May 17 FDA Statement, on May 17, 2021, the price of CytoDyn's common stock fell by $0.76 per share—more than 27%—from a close of $2.80 on May 14, 2021, to a close of $2.04 on May 17, 2021 on high trading volume.

380. Industry observers noted the FDA's unusual, severely negative response to CytoDyn, and the fact that it directly contradicted Defendants' repeated claims about a COVID-19 indication for leronlimab. For example, on May 17, 2021, Adam Feuerstein of *STAT+* issued an article entitled, "FDA issues major rebuke to CytoDyn over claims on Covid-19 drug," on the news and stated:

> The Food and Drug Administration on Monday took the extraordinary step of issuing a lengthy statement on an unapproved drug, rejecting claims made by the troubled drug maker CytoDyn about its failed antibody treatment for Covid-19.
>
> CytoDyn's CEO, Nader Pourhassan, has repeatedly touted the potential of the drug, leronlimab, on conference calls, YouTube videos, and in press releases, saying the treatment was shown to have saved lives in clinical trials.
>
> The FDA said it had determined otherwise.

381. The drastic and sudden decline in CytoDyn's stock price on May 17, 2021 was the direct result of Defendants' fraud regarding the Phase 2b/3 Trial (CD12) being further revealed to the market. The timing and magnitude of the decline negates any inference that it, or the related loss suffered by Plaintiffs and the Class, were caused by changed market conditions,

macroeconomic or industry factors, or Company-specific factors unrelated to Defendants' fraudulent conduct.

382. Defendants' wrongful conduct alleged herein directly and proximately caused the damages suffered by Plaintiffs and other Class members. Had Defendants disclosed complete, accurate, and truthful information during the Class Period, Plaintiffs and other Class members would not have purchased or otherwise acquired CytoDyn common stock at the artificially inflated prices that they paid. It was also entirely foreseeable to Defendants that misrepresenting and concealing material facts from the public would artificially inflate the price of CytoDyn common stock and that the ultimate disclosure of this information would cause the price of CytoDyn common stock to decline.

383. The economic loss, i.e., damages, suffered by Plaintiffs and other Class members directly resulted from Defendants' materially false or misleading statements and omissions of material fact, and their fraudulent scheme or course of conduct, which created or maintained artificial inflation in the price of CytoDyn common stock. When the truth was revealed in the disclosures as noted in this section, the price of CytoDyn common stock declined substantially as the market absorbed this information, causing Plaintiffs and other Class members to suffer economic losses.

VII. ADDITIONAL ALLEGATIONS OF SCIENTER

384. CytoDyn and the Individual Defendants were active and culpable participants in the fraud, as evidenced by their knowing or deliberately reckless issuance of and/or control over their materially false and misleading statements and omissions, and their active perpetration of the fraudulent scheme. Cytodyn, through its management, other senior level employees, and the Individual Defendants acted with scienter in that they knew or were deliberately reckless in disregarding that their public statements set forth in Section V above were materially false and misleading when made, and knowingly participated or acquiesced in the issuance or dissemination of such statements, or were deliberately reckless in so doing, as primary violators

of the federal securities laws. Similarly, the Defendants actively, knowingly and/or with deliberate recklessness participated in the fraudulent scheme alleged herein. In addition to the facts alleged in Section IV above, regarding CytoDyn's and the Individual Defendants' personal knowledge and/or deliberately reckless disregard of the materially false misrepresentations and omissions, and the Individual Defendants' motive and opportunity to commit the fraud, Defendants' scienter is evidenced by the specific facts discussed below.

A. Defendants Knew That the HIV BLA was Not Complete as of April 27, 2020 and May 11, 2020

385. CytoDyn submitted its purportedly "complete[]" HIV BLA to the FDA on or around April 27, 2020. On May 4, 2020, CytoDyn admitted that this HIV BLA submission was not complete but would be completed by May 11, 2020. Thereafter, Defendants confirmed that CytoDyn had resubmitted the purportedly "complete" HIV BLA on May 11, 2020.

386. On July 8, 2020, the FDA sent CytoDyn a 21-page RTF Letter signed by Dr. Debra B. Birnkrant "find[ing]" that the Company's HIV BLA "does not contain all pertinent information and data needed to complete a substantive review" and "has numerous omissions and inadequacies so severe as to render the application incomplete." The RTF Letter further stated, in relevant part, that the HIV BLA "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." Likewise, the RTF Letter noted that "the data quality issues" identified in the HIV BLA were "extensive," and concluded, "[t]he high number of data quality issues identified during the filing review indicate that the process used to construct ADaM datasets from SDTM datasets and produce CSRs from the analysis datasets may have been flawed."

387. As set forth herein, Defendants knew that the HIV BLA submitted on or around April 27, 2020 and resubmitted May 11, 2020 "d[id] not contain all pertinent information and data" required by the FDA to review the HIV BLA and otherwise knew that the HIV BLA "ha[d]

numerous omissions and inadequacies," including missing "substantial amounts" of data and datasets that required correction, in part to "extensive" "data quality issues," and was therefore, "incomplete."

1. Defendants Participated in Prior Meetings and Exchanged Correspondence with the FDA Regarding the Necessary Content of the HIV BLA

388. The July 8, 2020 RTF Letter plus Defendants' later correspondence with the SEC regarding the Company's FY20 Form 10-K revealed numerous meetings and correspondence between Defendants and the FDA prior to the submission of the HIV BLA on or around April 23, 2020 and resubmission on May 11, 2020.

389. **June 2018 Pre-BLA Meeting**. The FDA held a pre-HIV BLA meeting with CytoDyn in June 2018. During that meeting, and again in correspondence from November 2019, the FDA "requested" that CytoDyn "submit complete bioanalytical reports (reports which describe analysis of concentrations of leronlimab in blood samples collected in the clinical trials)." In a March 23, 2021 letter to the SEC that was signed by Defendant Mulholland (the "March 23, 2021 Letter"), CytoDyn confirmed that this meeting occurred on June 18, 2018, and that the FDA communicated, among other things, "the requirement for full validation data form all PPQ lots at the time of the BLA submission." Per the RTF Letter, "[d]espite the advice provided on two separate occasions, the bioanalytical reports [were] not included in" CytoDyn's HIV BLA submission.

390. **December 14, 2018 Teleconference**. In the March 23, 2021 Letter, CytoDyn stated that during a December 14, 2018 teleconference, the "FDA briefly reiterated the previous advice provided to CytoDyn regarding outstanding information to be completed prior to submission of BLA, where if not submitted in completed form, would be considered Refusal to File issues. These include[d] final CMC [Chemistry Manufacturing Controls] information, an agreed upon iPSP and final results from a Human Factors study." Despite the FDA's clear guidance, which CytoDyn confirms it received by December 2018, the RTF Letter confirmed

that the HIV BLA did not include, among other items, "data from studies conducted with the drug in the device . . . and no information . . . on the manufacturer of the syringe and needles."

391. **January 2019 MPPRC Meeting**. According to the FDA, following a January 2019 MPPRC meeting, DAV [Division of Antivirals] communicated the following comment: "Members of the Council asked about the CCR5 receptor occupancy data for the 350 mg, 525 mg and 700 mg doses. Please submit this data with your BLA." In its December 16, 2019 correspondence the FDA "reiterated this request." However, "[d]espite this advice," the RTF Letter confirmed that "the [HIV] BLA include[d] only representative data from 525 mg and 700 mg in the receptor occupancy report," which itself "does not adequately address numerous methodologic[al] concerns."

392. **January 16, 2019 Correspondence**. Prior to CytoDyn's January 16, 2019 correspondence, the FDA "requested a Pop PK analysis to support the selection of a higher dose [700 mg, based on the dose-finding study in the monotherapy study (CD03)] than the dose evaluated in the pivotal trial (CD02)." (Brackets in original.) In correspondence dated January 16, 2019, CytoDyn "described plans to use studies CD02, CD03, and CD06 . . . [for] the Pop PK analysis." Despite the FDA's clear guidance, and CytoDyn's acknowledgement of the same, the HIV BLA included an analysis that was not consistent with FDA guidance.

393. **January 22, 2019 Correspondence**. In correspondence dated January 22, 2019, the FDA provided CytoDyn "with specific advice for [its HIV] BLA submission wherein," the FDA "communicated CDER's Medical Policy and Program Review Council members' concerns about the possibility that [Anti-Drug Antibodies ("ADA")] may impact leronlimab effectiveness" and "[s]pecifically . . . advised [the Company] that the [HIV] BLA should include a detailed narrative to explain whether or not ADA is associated with virologic failure." Despite receiving this specific advice, the RTF Letter concluded that the HIV BLA "d[id] not include any analyses of [ADA] or any assessment of any association between ADA and virologic failure."

394. **November 11, 2019 Correspondence**. The FDA sent CytoDyn correspondence dated November 11, 2019 "that explain[ed] the importance of displaying CD03 data by randomization group." Despite this clear guidance, the RTF Letter found that the HIV BLA submitted on or around April 27, 2020 and resubmitted on May 11, 2020 did not include "an integrated assessment of efficacy," and "the comparisons of effectiveness by dose provided in the Summary of Clinical Efficacy and the CD03 CSR were conducted by dose group instead of between the randomized arms."

395. **December 16, 2019 Correspondence**. On December 16, 2019, the FDA sent CytoDyn a letter regarding its HIV BLA. In the letter, the FDA stated:

> With your BLA submission, you should submit an integrated assessment and detailed summary that supports your selected dose [700 mg] 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 data (including both method validation report and bioanalytical report of clinical samples). The integrated assessment should reflect data from the 3 doses evaluated in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02.

396. The FDA previously provided CytoDyn with similar advice on January 22, 2019, "following [the FDA's] presentation of the revised [HIV] BLA submission plan to the CDER's Medical Policy and Program Review Council (MPPRC)." Additionally, in a June 3, 2019 correspondence, the FDA informed CytoDyn that the "2-page 'Rationale Dose Section'" the Company "provided with [its] proposed CD08 trial . . . was insufficient." Despite this clear guidance, the RTF Letter determined that HIV BLA submitted on or around April 27, 2020 and resubmitted on May 11, 2020 did not include or was otherwise missing: (i) "the information and analyses needed to permit FDA reviewers (clinical, statistical, clinical virology and clinical pharmacology) to perform a substantive review of the proposed dose"; (ii) "an integrated assessment that incorporates detailed summaries reflecting data from the participants randomized

to receive 350 mg, 525mg, and 700mg in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02"; and (iii) "multiple reports that are needed to permit a substantive review."

397. As such, Defendants were aware of the information the FDA expected to see in the HIV BLA submission in order for it to be "complete" and, therefore, knew that the HIV BLA submitted on or around April 27, 2020 and resubmitted on May 11, 2020 was not "complete" and, in fact, "has numerous omissions and inadequacies so severe as to render the application incomplete."

2. CytoDyn's CRO, Amarex, Warned Defendants That the HIV BLA was Not Complete before the Company Submitted It on or around April 27, 2020; Pourhassan Directed Amarex to File It Anyway

398. In a sworn declaration filed in *CytoDyn, Inc. v. Amarex Clinical Research, LLC*, No. 21-cv-2533, co-founder, President, and CEO of Amarex, Kazempour, stated that Amarex "warned" Defendant Pourhassan about the incomplete HIV BLA. Nevertheless, on April 14, 2020, "Pourhassan directed Amarex to file the BLA prematurely, knowing it was incomplete, lacking in appropriate content and not ready for submission." In an email, which was attached to Kazempour Decl. as Exhibit C, Pourhassan wrote, in relevant part, "[p]lease 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." Accordingly, "[a]t [Defendant] Pourhassan's director, Amarex submitted the incomplete and lacking [HIV] BLA to the FDA."

3. CytoDyn's Management, Including Defendants Pourhassan and Mulholland, Nevertheless Purportedly Determined That FDA Approval of Leronlimab for HIV was Probable as of February 29, 2020

399. In a March 23, 2021 Letter to the SEC, CytoDyn stated that its "management," which would include at least Defendants Pourhassan and Mulholland, purportedly "determined that FDA approval of leronlimab was probable during the quarter ended February 29, 2020" based on their "belie[f that] the remaining two components of the Company's BLA (clinical and

CMC) were nearly complete and the two remaining components would be filed before fiscal year ended May 31, 2020."

400. In order to determine that FDA approval was probable, CytoDyn's "management," including at least Defendants Pourhassan and Mulholland, would have needed to know the status of the HIV BLA and, ultimately, whether what was submitted on or around April 27, 2020 and resubmitted on May 11, 2020 contained all of the required components and was otherwise "complete." However, as confirmed by Amarex's CEO, Kashpour's sworn declaration and Defendant Pourhassan's April 14, 2020 email, the HIV BLA was not complete as of February 29, 2020, nor was it complete on or around April 27, 2020 when it was submitted to the FDA or on May 11, 2020 when it was resubmitted to the FDA.

B. Defendants Knew the Information Contained in the FDA's May 17, 2021 Statement on Leronlimab before They Made Materially False and Misleading Statements about the Safety and Efficacy of Leronlimab and the Results of the Phase 2 Trial (CD10) and the Phase 2b/3 Trial (CD12)

401. Prior to making statements about the safety and efficacy of leronlimab for COVID-19 or the results of the Phase 2 and Phase 2b/3 Trials, Defendants had frequent interactions with the FDA concerning the potential use of leronlimab to treat COVID-19. *See* Sections IV.A.; VII.A.

402. Prior to making materially false and misleading statements regarding the safety and efficacy of leronlimab for treating COVID-19, Defendants knew that the FDA had not made any determinations about the safety and efficacy of leronlimab in any indication, including HIV, cancer, and COVID-19. Moreover, as a result of the July 8, 2020 RTF Letter, Defendants knew that the FDA had not been able to engage in a "[s]ubstantive [r]eview of [p]roduct [e]ffectiveness and [s]afety" as part of the HIV BLA because of the "[a]bsence of [d]emographic [s]ubset [a]nalyses," among other issues. As a result, they knew "that the data [then] available d[id] not support the clinical benefit of leronlimab for the treatment of COVID-19."

403. Prior to making materially false and misleading statement regarding the Phase 2 Trial (CD10) results, Defendants had in their possession the unblinded safety and efficacy data from that trial, as well as the relevant statistical analyses of that data. They also had in their possession that "top-line" report CytoDyn submitted to the FDA and other foreign regulatory agencies.

404. As a result, Defendants knew at least the following before they made materially false and misleading statements concerning the results of the Phase 2 Trial (CD10): (i) "that the data [then] available d[id] not support the clinical benefit of leronlimab for the treatment of COVID-19"; (ii) "there was no observed effect of the drug on the study's primary endpoint or on any of the secondary endpoints" in the Phase 2 Trial (CD10); (iii) "[t]he CD10 trial results showed no clinically meaningful differences in [the primary endpoint] from baseline to Day 14 between study arms"; (iv) "none of the secondary endpoints were met in this study [Phase 2 Trial (CD10)], including mortality, time to symptom resolution, and time to return to normal activity"; and (v) "the CD10 results indicate that most study participants experienced resolution in COVID-19 symptoms regardless of whether they received leronlimab or placebo." Defendants likewise knew that the FDA would not grant it a EUA based on the results of the Phase 2 Trial (CD10) when CytoDyn announced that it had submitted such a request to the FDA.

405. Prior to making materially false and misleading statement regarding the Phase 2b/3 Trial (CD12) Results, Defendants had in their possession the unblinded safety and efficacy data from that trial, as well as the relevant statistical analyses of that data, including the "age adjustment" analysis disclosed in the March 6, 2021 press release. Indeed, the "Executive Summary" of the Phase 2b/3 Trial (CD12) results (which included the age adjustment analysis) that CytoDyn filed with the SEC as an exhibit to a Form 8-K signed by Defendant Mulholland was dated March 4, 2021, the day before the first press release the Company issued. Defendants also had in their possession that "top-line" report CytoDyn submitted to the FDA and other foreign regulatory agencies. Additionally, Defendants had in their possession the "further

statistical analysis" disclosed to investors in a March 30, 2021 press release prior to making materially false and misleading statements concerning that analysis.

406. As a result, Defendants knew at least the following before they made materially false and misleading statements concerning the results of the Phase 2b/3 Trial (CD12): (i) "that the data [then] available d[id] not support the clinical benefit of leronlimab for the treatment of COVID-19"; (ii) the Phase 2b/3 Trial (CD12) "failed to find any effect of the drug on the primary study endpoint, with no difference seen in mortality[,]. . . or on any of the secondary endpoints"; (iii) "[s]ubgroup 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"; (iv) "[n]one" of the Phase 2b/3 Trial (CD12) subgroup "analyses met statistical significance when using established and reliable analytical methods that correct for multiple comparisons"; and (v) when "the analyses of the primary and secondary endpoints do not support conclusions of the medicine's benefit," as was the case here, analyses of subgroups (even if "prespecified") "do not support reliable conclusions about the medicine's benefit."

C. Defendants Were Motivated to Make Materially False and Misleading Statements Regarding the HIV BLA and COVID-19 and Engage in a Stock Promotion Scheme in Violation of Section 10(b) and Rule 10b-5(a-c)

1. Defendants' Stock Sales

a. Defendants Grant Themselves Millions in Options & Warrants in December 2019

407. On December 19, 2019, after two successive positive press releases on December 3 and December 17, 2019, Pourhassan and Kelly, granted themselves, Mulholland and Dr. Patterson, among others, an aggregate of 9.3 million stock options/warrants with an exercise price of $0.63 per share, the closing price of CytoDyn's common stock on December 19, 2019 ("December 2019 Awards"):

NAME	POSITION	OPTIONS/WARRANTS
Defendant Pourhassan	CEO	4,000,000
Defendant Kelly	Non-Employee Director/Consultant	1,250,000
Defendant Mulholland	SVP of Finance	700,000
Dr. Patterson	Consultant	200,000
Michael A. Klump ("Klump")	Non-Employee Director	750,000
Jordan G. Naydenov ("Naydenov")	Non-Employee Director	750,000
David F. Welch ("Welch")	Non-Employee Director/Consultant	750,000
Ray	Chief Technology Officer	600,000
Brendan Rae	SVP	300,000
TOTAL		**9,300,000**

408. While 6,050,00 of the December 2019 Awards vested immediately, 2 million warrant shares granted Pourhassan, 500,000 of the options granted Kelly, and 350,000 of the options granted to Mulholland would vest "on the date on which [CytoDyn] files its BLA for HIV combination therapy with the FDA." (Alteration in original.) Accordingly, each of the Individual Defendants were motivated to file the HIV BLA in order to obtain access to these options/warrants. And, tellingly, after knowingly causing CytoDyn to file a materially incomplete HIV BLA with the FDA on or around April 27, 2020, Defendant Pourhassan immediately exercised two million of the options/warrants he improperly awarded himself for December 2019, selling at least 70% of the resulting shares over three trading days starting April 30, 2020.

409. As described in the verified *Alpha Ventures* complaint (and "revealed in the documents produced in [response to a] Section 220 [d]emand"), "the December 2019 Awards

were the result of a hastily called telephonic meeting" on the evening of December 19, "arranged by Pourhassan" to discuss his "[r]ecommendations . . . regarding stock option awards" or, in other words, so that he could propose granting himself four million options/warrants. In addition to Pourhassan, Defendants Kelly and Mulholland both attended the December 19 Board meeting.

410. According to the verified *Alpha Ventures* complaint, the December 2019 Awards were "[i]n violation of the Compensation Committee Charter." Moreover, internal documents demonstrate that after the Board approved the December 2019 Awards, CytoDyn's then-CFO Eastwood emailed Defendants Pourhassan and Mulholland a spreadsheet purporting to show that the December 2019 Awards were comparable to other "stock options held by boards and management of similarly situated companies." The spreadsheet "provide[d] no insight whatsoever as to the value of any of the[] stock options" reflected therein, and the listed companies had "little in common" with CytoDyn.

411. The verified *Alpha Ventures* complaint described the December 19, 2019 Board meeting and resulting December 2019 Awards as a "procedural sham" and "an outrageous act of collective self-dealing and blatant disregard for fiduciary obligations." The verified *Alpha Ventures* complaint further stated that Defendant Pourhassan's four million options/warrants, the fair value of which was $1.16 million, "was the largest stock option award he ever received from the Company, and it nearly equaled the total value of his [FY] 2019 compensation package" (discussed herein). Moreover, the verified *Alpha Ventures* complaint contended that the December 2019 Awards were "spring-loaded" or their issuance "deliberately timed . . . just prior to the release of positive financial information in order to lock in a low exercise price," citing a December 23, 2019 press release (two business days after the December 2019 Awards) announcing positive results concerning the use of leronlimab to treat breast cancer. By December 27, 2019, the December 2019 Awards were in the money by $0.35 per share.

412. But, Defendants Pourhassan and Kelly were not done. On January 18, 2020—a Saturday—Defendants awarded themselves and others 11.65 million shares (the "January 2020

Awards"), with Pourhassan and Kelly receiving an equity awards of 6 million shares (valued at $6.3 million and exceeding all of the compensation he had received as CEO for five years) and 2.5 million shares (valued at $2.625 million), respectively, which would vest if CytoDyn "achieve[d] Breakthrough Therapy Designation within 6 months from January 27, 2020." Notably, these awards would have automatically settled in shares of common stock and are not subject to an exercise price—in other words, Defendants Pourhassan and Kelly were set to receive a massive amount of equity in CytoDyn without paying any cash to the Company.

413. According to the verified *Alpha Ventures* complaint, "[t]he January 2020 Awards were so egregious that Klump refused to participate" and resigned from the Board on January 15, 2020. Although CytoDyn stated that Klump's resignation was "not related to any known disagreement with" CytoDyn, Gould, Dockery, and Caracciolo alleged in the verified *Alpha Ventures* complaint based on their personal knowledge that "Klump resigned from the Board because, as he has expressed to another stockholder, he had simply 'had enough' of Pourhassan's repeated misconduct and did not want to risk incurring personal liability."

414. Further, the verified *Alpha Ventures* complaint stated that per "the minutes of the January 2020 Meeting, Kelly 'advised' the Board of a 'proposed issuance' of 11,650,000 shares." Following 30 minutes of discussion, the Board approved the January 2020 Awards without "review[ing] any peer analysis" and in violation of the Compensation Committee Charter.

415. While CytoDyn did not achieve a Breakthrough Therapy Designation within six months and the January 2020 Awards did not vest, the December 2019 and January 2020 Awards were the subject of a lawsuit—*Alpha Ventures*—filed by Gould, Dockery, Caracciolo, and others derivatively on behalf of CytoDyn against Defendants Pourhassan, Kelly and Mulholland, among others, on April 24, 2020—three days before Defendants claimed that the HIV BLA was "completed" when they knew otherwise and just five days before Defendant Pourhassan

exercised and sold 2 million warrants granted him in December 2019, selling at least 70% of the resulting shares beginning on April 30, 2021.

416. On May 4, 2020, the Board formed a special litigation committee ("SLC") to investigate the Alpha Ventures' claims. The SLC in turn adopted resolutions prohibiting Defendants Pourhassan, Kelly, and Mulholland among others, from exercising or selling any of the challenged "awards going forward unless the proceeds from any such exercise or sale are placed in escrow."

417. In December 2020, the SLC settled with Pourhassan and Kelly, among others. As part of the settlement, Pourhassan forfeited the remaining 2 million options/warrants he had not exercised and sold before he was prevented from doing so and 373,000 options that were issued separate and apart from the December 2019 Awards, and Kelly forfeited 60% of the December 2019 Awards or 750,000 options.

418. On June 4, 2021, the Delaware Chancery Court approved the *Alpha Ventures* settlement, requiring Defendants Pourhassan and Kelly, among others, to return Cytodyn stock options and warrants they had improperly granted themselves in December 2019 (or their equivalent). During an April 19, 2021 hearing regarding the settlement, the Delaware Chancery Court raised this litigation, stating, "[t]here's other litigation that's out there . . . challenging the exercise of options by the CEO, Mr. Pourhassan, and Mr. Mulholland that are alleged to have been . . . a pump-and-dump." With respect to the award of the December 2019 and January 2020 options and warrants, the Court further stated,

> I am deeply troubled by the behavior of the defendants [i.e., Pourhassan and Kelly] in approving these awards. Based upon the record, this strikes me as a case of unmitigated greed. Not only was there no process and not even a pretense of evaluating the fairness of these grants, but the leaders of this compensation decision rejected legal advice and withheld legal advice from some of the directors. . . . I am also concerned that the [Special Litigation Committee] allowed the mastermind of these awards, Mr. Pourhassan, to keep the equivalent of 40 percent of his awards . . . [and] the settlement does not expressly prohibit any attempt to grant replacement awards or other compensation to replace what has been forfeited in the settlement.

419. Despite the Court's expressed concern, on October 20, 2021, CytoDyn awarded Defendants Pourhassan and Kelly 4,275,000 stock options and 1,750,000 stock options, respectively.

b. Defendants' Class Period Stock Sales Were Unusual and Suspicious

420. During the Class Period, Defendants Pourhassan, Kelly, and Mulholland collectively disposed of more than $30 million in CytoDyn common stock while in possession of adverse material, nonpublic information regarding the completeness of the Company HIV BLA and as part of a stock promotion fraud tied to COVID-19. As a result of Defendants' materially false and misleading statements and omissions of material fact, as well as their execution of a stock promotion fraud, these stock dispositions were executed at artificially inflated prices under suspicious circumstances.

421. During the Class Period, Defendant Pourhassan exercised options and warrants at exercise prices between $0.39 and $1.09 per share and then disposed of 4,977,744 shares at sales prices between $2.7904 and $4.97, for total proceeds of $16,539,062.76. Defendant Pourhassan's trades are set forth in the following chart:

DEFENDANT POURHASSAN					
Transaction Date	**Acquired/ Disposed**	**No. of Shares**	**Exercise Price**	**Sale Price**	**Proceeds**
4/30/2020	Acquired	200,000	$0.9		
4/30/2020	Acquired	325,000	$0.87		
4/30/2020	Acquired	152,000	$0.75		
4/30/2020	Acquired	600,000	$1.09		
4/30/2020	Acquired	199,800	$0.57		
4/30/2020	Acquired	600,000	$0.8		
4/30/2020	Acquired	116,550	$0.49		

DEFENDANT POURHASSAN					
Transaction Date	**Acquired/ Disposed**	**No. of Shares**	**Exercise Price**	**Sale Price**	**Proceeds**
4/30/2020	Acquired	1,000,000	$0.565		
4/30/2020	Acquired	187,817	$0.39		
4/30/2020	Acquired	2,000,000	$0.63		
4/30/2020	Disposed	2,219,837		$3.5312[10]	**$7,838,688.41**
5/1/2020	Disposed	1,399,685		$3.2644[11]	**$4,569,131.71**
5/4/2020	Acquired	30,933	$0.39		
5/4/2020	Disposed	1,201,652		$2.7904[12]	**$3,353,089.74**
7/31/2020	Acquired	323,157	$0.00		
7/31/2020	Disposed	156,570		$4.97	**$778,152.90**
TOTAL DISPOSED		**4,977,744**	**TOTAL PROCEEDS**		**$16,539,062.76**

422. During the Class Period, Defendant Kelly exercised 1,200,000 stock options at exercise prices between $0.385 and $0.61 per share and then disposed of 1,200,000 shares at a sales price of $3.2064, for total proceeds of $3,912,480. Defendant Kelly's trades are set forth in the following chart:

[10] This transaction was executed in multiple trades at prices ranging from $3.44 to $3.74. The price above reflects the weighted-average sale price.

[11] This transaction was executed in multiple trades at prices ranging from $3.13 to $3.54. The price above reflects the weighted-average sale price.

[12] This transaction was executed in multiple trades at prices ranging from $2.53 to $3.00. The price above reflects the weighted-average sale price.

DEFENDANT KELLY					
Transaction Date	**Acquired/ Disposed**	**No. of Shares**	**Exercise Price**	**Sale Price**	**Proceeds**
5/1/2020	Acquired	7,123	$0.61	--	
5/1/2020	Acquired	75,000	$0.57	--	
5/1/2020	Acquired	97,009	$0.56	--	
5/1/2020	Acquired	100,000	$0.49	--	
5/1/2020	Acquired	250,000	$0.565	--	
5/1/2020	Acquired	66,666	$0.52	--	
5/1/2020	Acquired	750,000	$0.385	--	
5/1/2020	Acquired	93,750	$0.39	--	
5/1/2020	**Disposed**	**1,200,000**	**--**	**$3.2604**[13]	**$3,912,480**
TOTAL DISPOSED		**1,200,000**	**TOTAL PROCEEDS**		**$3,912,480**

423. During the Class Period, Defendant Mulholland exercised stock options at exercise prices over four consecutive trading days between $0.39 and $1.40 per share then disposed of 1,816,600 at sales prices between $4.5523 and $7.00 per share, for total proceeds of $10,264,588.75. Mulholland's trades were transacted pursuant to a 10b5-1 trading plan that he executed in November 2020, during the Class Period. Defendant Mulholland's trades are set forth in the following chart:

[13] This transaction was executed in multiple trades at prices ranging from $3.16 to $3.37. The price above reflects the weighted-average sale price.

DEFENDANT MULHOLLAND					
Transaction Date	**Acquired/ Disposed**	**No. of Shares**	**Exercise Price**	**Sale Price**	**Proceeds**
12/17/2020	Acquired	32,000	$0.39		
12/17/2020	Disposed	**32,000**		$4.5523[14]	**$145,673.60**
12/18/2020	Acquired	155,550	$0.39		
12/18/2020	Acquired	233,100	$0.49		
12/18/2020	Acquired	98,402	$0.57		
12/18/2020	Disposed	**487,002**		$4.9516[15]	**$2,411,439.10**
12/21/2020	Acquired	201,598	$0.57		
12/21/2020	Acquired	300,000	$0.80		
12/21/2020	Acquired	88,199	$0.87		
12/21/2020	Disposed	**585,797**		$5.582[16]	**$3,269,918.85**
12/22/2020	Acquired	161,801	$0.87		
12/22/2020	Acquired	150,000	$0.9		
12/22/2020	Acquired	300,000	$1.09		
12/22/2020	Acquired	100,000	$1.4		
12/22/2020	Disposed	**245,704**		$5.4938[17]	**$1,349,848.64**
12/22/2020	Disposed	**453,997**		$6.6146[18]	**$3,003,008.56**

[14] This transaction was executed in multiple trades at prices ranging from $4.50 to $4.68. The price above reflects the weighted-average sale price.

[15] This transaction was executed in multiple trades at prices ranging from $4.80 to $5.08. The price above reflects the weighted-average sale price.

[16] This transaction was executed in multiple trades at prices ranging from $5.03 to $6.00. The price above reflects the weighted-average sale price.

[17] This transaction was executed in multiple trades at prices ranging from $5.03 to $5.98. The price above reflects the weighted-average sale price.

[18] This transaction was executed in multiple trades at prices ranging from $6.02 to $6.99. The price above reflects the weighted-average sale price.

DEFENDANT MULHOLLAND					
Transaction Date	**Acquired/ Disposed**	**No. of Shares**	**Exercise Price**	**Sale Price**	**Proceeds**
12/22/2020	Disposed	**12,100**		$7.00	**$84,700.00**
TOTAL DISPOSED		**1,816,600**	**TOTAL PROCEEDS**		**$10,264,588.75**

424. Both the amount and timing of Pourhassan's, Kelly's, and Mulholland's trades were highly unusual and suspicious. As set forth above, Pourhassan exercised and sold 4.8 million options/warrants, some of which he improperly granted himself as part of the December 2019 Awards less than a week after the *Alpha Ventures* complaint was filed challenging those awards, three business days after Defendants told investors CytoDyn had filed with the FDA a completed HIV BLA. Moreover, Pourhassen made 75% of his transactions before CytoDyn revealed the relevant truth regarding the April 2020 HIV BLA submission by burying it in a May 4, 2020 press release. Defendant Kelly likewise made all of his sales after Defendants told investors that the April 2020 HIV BLA was "completed" and before the Company revealed the relevant truth buried in the May 4, 2020 press release.

425. Defendant Mulholland, on the other hand, waited to transact in CytoDyn's common stock until after the stock price had cleared both the $3.00 and $4.00 NASDAQ stock price threshold after months of trading below these thresholds. Additionally, Defendant Mulholland sold a majority of his shares at weighted average prices above or around $5.00 per share; CytoDyn shares only had closed above $5.00 per share less than two dozen times between March 27, 2020 and December 17, 2020.

426. The Individual Defendants' Class Period trades were also suspicious because they were dramatically out of line with their prior trading history. For example, Defendant Pourhassan's last sale was in 2011, nearly nine years earlier. Moreover, prior to the Class Period,

neither Kelly nor Mulholland had sold any CytoDyn shares. Additionally, neither Kelly nor Mulholland have sold any shares since their Class Period transactions.

2. Defendant Pourhassan's Compensation Supports a Strong Inference of Scienter

427. Defendant Pourhassan's compensation, and in particular, his tactics to achieve materially increased compensation at the expense of CytoDyn, support an inference of scienter.

428. CytoDyn executive compensation typically includes a base salary, a potential bonus tied to performance objectives, and an annual award of stock options under the Incentive Plan. The Compensation Committee—a board-level committee—is responsible for CytoDyn's executive compensation program. According to the Compensation Committee's charter, it must be comprised of at least two independent directors. With Gould's and Dockery's resignations from the CytoDyn Board on August 12, 2019 and September 12, 2019, respectively, the Board was comprised of just five members, Pourhassan, Kelly, Klump, Naydenov, and Welch, only two of which were independent (Klump and Naydenov) due to lucrative consulting agreements Kelly and Welch, respectively, had entered into with CytoDyn in the summer of 2019. Despite this, the Board appointed Welch to serve on the Compensation Committee with its only other member, Naydenov.

429. According to the *Alpha Ventures* verified complaint, Defendant Pourhassan's "incessant demands for increased compensation caused significant disruption at the Board level and, in part, led to the departures of Dockery and Gould from the Board." According to Dockery's, Gould's, and Caracciolo's verified allegations based upon their personal knowledge, "Pourhassan consistently and aggressively lobbied the Board for more compensation using various dishonest and self-serving tactics." These former CytoDyn directors claimed that "[a]t almost every [CytoDyn] Board meeting, Pourhassan would begin with a presentation about all the things he was doing for the Company and the financial sacrifices he had purportedly

made . . . to complain that he was underpaid and entitled to additional (but undeserved) compensation."

430. Dockery, Gould, and Caracciolo also claimed that Defendant Pourhassan "repeatedly demanded to be paid in full even when he failed to meet his agreed-upon goals, and often demanded that the Compensation Committee extend the relevant period of time . . . [for] his goals or allow the goals to carry forward into the next year" with Pourhassan still receiving the full bonus for the year at issue. Likewise, these former CytoDyn directors confirmed that "Pourhassan repeatedly complained that his compensation was not paid sufficiently in cash (as opposed to stock), and that he wanted" more cash than equity. Pourhassan also "floated the idea that he should be compensated based on a percentage of the funds 'he' purportedly raised for" CytoDyn and when at least Gould explained to him that it was illegal to do so, "Pourhassan reacted negatively and insisted that he was being treated unfairly by certain directors who would not accede to his demands." As a result, Dockery, Gould, and Caracciolo alleged in their verified complaint that "Pourhassan made no secret of the fact that he placed his own financial interests above protecting the Company's work and future."

431. Per the *Alpha Ventures* verified complaint, Defendant Kelly supported Pourhassan when he claimed "that [CytoDyn] investors would not 'respect' him unless the Company paid him more" and, per the former CytoDyn directors "felt that Pourhassan should be kept happy due to the risk his sudden departure may have on [CytoDyn's] operations." This included assisting Pourhassan in perpetrating a fraud on the Compensation Committee with respect to his FY19 compensation, which totaled $1,520,534 and included, *inter alia*, a base salary of $506,160, a potential bonus valued at $683,290, and stock awards valued at $312,936. During a June 16, 2019 meeting of the Compensation Committee (of which Defendant Kelly was then a member), Kelly stated that the former chairman of the Compensation Committee, Bruce Montgomery, had "approved an incentive-based goal whereby Pourhassan would receive a bonus of no less than 110% of his annual salary solely by meeting a fundraising goal." Per Dockery and Gould, who

both attended the June 2019 meeting, Kelly told the Compensation Committee that they would have to honor this promise or "risk causing Pourhassan to 'melt down' or 'take other actions' that would harm the Company." Ultimately, the Compensation Committee approved a bonus of 135% of Pourhassan's base compensation for FY19.

432. Later, Dockery and Gould discovered that there was "no documentary evidence of the alleged promise" and learned from Montgomery himself "that no such 'promise' had been made to Pourhassan." When confronted, Kelly stated that it was, in fact, Caracciolo (not Montgomery) who had made the promise to Pourhassan. Per Caracciolo, "[t]hat too was a lie." By July 2019, Kelly and Pourhassan had successfully caused CytoDyn's Board to "vote[] to remove Dockery and Gould from the Board-approved slate of directors that would stand for reelection."

433. For FY19, which ended May 31, 2019, Defendant Pourhassan received $1,520,534 in total compensation. This was consistent with the total compensation approved by CytoDyn's Board prior to Dockery's and Gould's resignations.

434. For FY20, which ended May 31, 2020, Defendant Pourhassan received $9,971,254 in total compensation (a 555% y-o-y increase), including, inter alia, $865,671 in base salary (a 70% y-o-y increase), $617,500 in bonus (a 10% y-o-y decline), $1,242,150 in stock option awards (a 300% y-o-y increase), and $7,200,000 in stock awards (no awards were granted in FY2019).

435. For FY21, which ended May 31, 2021, Defendant Pourhassan received $10,045,507 in total compensation (a less than 1% y-o-y increase), including, inter alia, $1,000,000 in base salary (a 16% y-o-y increase), $1,000,000 in bonus split 80% cash and 20% fully vested CytoDyn shares (a 62% y-o-y increase), $3,750,090 in stock awards (a 48% y-o-y decrease), and $4,238,000 in stock option awards (a 240% y-o-y increase). Notably, Defendant Pourhassan's FY21 bonus payment "represent[s] supplemental bonuses paid in July 2020 in recognition of significant achievements during the quarter ended August 31, 2020."

D. Defendant Pourhassan Pushed Out or Terminated Any CytoDyn Board Member or Executive Who Questioned His Tactics or Decisions

436. Leading up to and during the Class Period, CytoDyn underwent significant Board and personnel changes as Defendants Pourhassan and Kelly sought to remove or freeze out any dissenters or individuals who would stand in the way of their fraudulent schemes.

437. **Caracciolo, Burger, and Montgomery**. After they pushed back on Pourhassan's demands for increased compensation, Burger and Montgomery resigned from CytoDyn's Board by the end of 2018, and Caracciolo resigned as Chairman of the Board on December 10, 2018 and as a director of CytoDyn on January 10, 2019, ending a six year run as a director on CytoDyn's Board.

438. **Dr. Pestell**. In 2018, CytoDyn purchased Dr. Pestell's biotechnology start-up, ProstaGene. As part of the transaction, the Company appointed Dr. Pestell its CMO as of November 2018. Dr. Pestell worked closely with Pourhassan. According to his later lawsuit, "[f]rom time to time, Dr. Pestell raised concerns regarding certain actions taken by the CEO, including but not limited to actions in connection with public representations" and "regulatory submissions," among other actions. Defendant Pourhassan's and Dr. Pestell's "relationship rapidly deteriorated following Dr. Pestell's objections in late June 2019" to an IND and protocol that CytoDyn planned to submit to the FDA "despite the fact that Dr. Pestell . . . determined that the protocol . . . was not safe for the study subjects." On July 1, 2019, Pourhassan emailed CytoDyn's Board (including Kelly), copying Mulholland, seeking permission to terminate Dr. Pestell for cause and appoint Kelly as CMO. When this plan did not come to fruition, on July 14, 2019, Pourhassan proposed and the CytoDyn Board approved naming Kelly Chief Science Officer and giving him many of Dr. Pestell's CMO responsibilities. After Dr. Pestell sent a letter from his counsel regarding these events, Pourhassan engineered a CytoDyn Board meeting at which Dr. Pestell was terminated for cause.

439. Notably, Dr. Pestell's former company, ProstaGene, filed an action in the Delaware Chancery Court to enforce a $7 million arbitration award against CytoDyn for its failure to turn over shares due to ProstaGene under its merger agreement with CytoDyn. The arbitration panel found, at the conclusion of the proceeding, that: (i) CytoDyn had proceeded with an FDA 501(k) presubmission that lacked necessary clinical lab testing, which showed "that CytoDyn's principal motivation was to use favorable press to attract financing and improve its stock price"; and (ii) that over Dr. Pestell's urging to complete needed clinical studies, "CytoDyn, apparently for marketing purposes, rushed to submit and announce a 510(k) presubmission without having conducted clinical studies, including completing a design verification process."

440. **Gould and Dockery**. In the verified *Alpha Venture* complaint Gould and Dockery asserted that "Pourhassan's incessant demands for increased compensation" was one of the reasons why they resigned from CytoDyn's Board. Nevertheless, as of June 2019, both Gould and Dockery were part of the CytoDyn Board-approved slate of directors who would stand for reelection later that year. However, after Gould expressed his objection to the proposed termination of CytoDyn's then-CMO Dr. Pestell to Defendant Kelly in July 2019, "Kelly intentionally put the matter to a Board vote when he knew Gould would be on an airplane and unavailable . . . after expressly telling Gould that he [Kelly] would not put Pestell's termination to a vote while Gould was not available."

441. For his part, Dockery sent letters to CytoDyn's Board and its auditor, Warren Averett, alerting them to Pourhassan's conduct and, in particular, his false and misleading statements to investors. In an August 30, 2019 letter to CytoDyn's outside auditor, Dockery asserted that Pourhassan's December 11, 2018 statement that "[b]y the end of the first quarter of 2019, we should have all of our BLA modules submitted to the FDA" was knowing false (or, at best, "utterly reckless") because "Pourhassan knew this was an unreasonable timeline when he made the statement." In a November 27, 2019 letter to CytoDyn's Board, Dockery asserted that

CytoDyn's December 12, 2018 press release stating "that it plans to seek FDA approval for leronlimab in combination therapy [for HIV] and to" file a BLA "in the first quarter of 2019 for that indication," while Pourhassan and the CytoDyn Board (including Kelly) "were informed that Q1 2019 was not a realistic timeframe." Dockery concluded, in relevant part: "Pourhassan has made a number of [] public statements touting the advancement of the Company's drug, revenue, and medical milestones that, at best, appear to be grossly overoptimistic. These statements, put together over time, might also be interpreted as conditioning the retail market to induce an investment with less than accurate information."

442. **Lowenstein**. Lowenstein served as CytoDyn's outside corporate counsel prior to the start of the Class Period. According to an August 30, 2019 letter Dockery provided to CytoDyn's auditor, Warren Averett, LLC, "during late 2018 and the early months of 2019, the Board discussed with" Pourhassan "that press releases and public statements by the CEO (including investor calls) needed to involve the Board and go through a more rigorous process to ensure their accuracy and tone." Dockery's letter stated that shortly after these discussions, Defendant Pourhassan "attempted to fire the attorney at Lowenstein Sandler LLP that had been attempting to help him with press releases and public statements" and claimed that "Pestell and [Dockery] prevented that from happening." At some point before January 18, 2020, Lowenstein Sandler was either terminated or resigned as the Company's counsel.

443. **Klump**. Following the departures of Denis R. Burger, A. Bruce Montgomery, Caracciolo, Gould, and Dockery, CytoDyn's Board included just five members, Pourhassan, Kelly, Welch, Klump, and Naydenov, of the non-executive members of the Board, Kelly and Welch were no-longer considered independent after CytoDyn retained them both as consultants in the summer of 2019. As explained above and in the verified *Alpha Ventures* complaint, Klump resigned from the CytoDyn Board on January 15, 2020, three days before Pourhassan and Kelly awarded themselves and others 11.65 million in stock that vested upon the issuance of a Breakthrough Therapy Designation.

444. **Eastwood**. In an 8-K filed on April 23, 2020, six days after Pourhassan directed Amarex to file an incomplete HIV BLA on CytoDyn's behalf and four days before Defendants announced that BLA was purportedly "complete," CytoDyn announced that Eastwood left the Company effective April 23, 2020, after only six months in the role, and appointed Mulholland as the interim CFO effective immediately. CytoDyn considered Eastwood's departure as a "termination without cause." CytoDyn formally named Mulholland as CFO on May 27, 2020.

E. Red Flags of a Pump-and-Dump Scheme

1. The Presence of Red Flags and Warning Signs of Microcap Fraud Supports a Strong Inference of Scienter

445. The SEC has identified "red flags" and "warning signs of microcap fraud," including: (i) an "[i]ncrease in stock price or trading volume linked to promotional activity"; *see generally* Section IV.F; (ii) "[p]ress releases or promotional activity announcing events that ultimately do not happen (e.g., contracts expected to produce revenue that never get finalized)"; (iii) the "[c]ompany issues a lot of shares without a corresponding increase in the company's assets"; (iv) the use of stock promotion and stock promotion services; and (v) "[n]o history of operational success" but the company "still projects large future revenues, especially if the projections appear [to be] based solely on information about the company's industry rather than on the company itself." Each of these red flags or warnings signs was present at CytoDyn during the Class Period.

a. Red Flag: Defendants Issued Press Releases and Engaged in Promotional Activity Touting Events, Milestones, or Actions That Ultimately Did Not Happen

446. One "red flag" or "warning sign" of stock promotion fraud is press releases or promotional activity announcing events that ultimately do not happen. Here, Defendants use of press releases nearly doubled during the Class Period. On certain days, Defendants issued multiple press releases about the same topic, sometimes 15 minutes apart, before or after the markets opened for trading in the U.S. A majority of these press releases concerned the use of

leronlimab to treat COVID-19. As explained in detail below in Section VII.E.3, Defendants also engaged in substantial promotional activity during the Class Period.

447. The story of these press releases and promotional activity is littered with examples of announcing events that ultimately did not happen, milestones that were not met, and actions that did not come to fruition. While a sampling of these events, milestones, and actions are discussed herein, the following statement from Defendant Pourhassan exemplifies this particular red flag:

> [T]he stock took off. What happened? How did it take off? We had national coverage [and positive eIND Results]. Those event[s] caused us to go from 3,500 investors to 43,000 [investors]. This stock took off and then the shorts saw the opportunity to attack us and they did. And now the stock hasn't moved. And I just got done telling the whole shareholder base that, please remember, if you going to make this decision about your stock sell or purchase, where are we now versus then ? . . . . ***We could be the only product [for COVID-19 long haulers]***. ***We are filing the protocol next week and we could have the enrollment finished this year in long haul.*** Do you want to sell shares ahead of that?. . . . ***We will follow [up] with Canada Health. And this is . . . COVID-19 and Cancer and HIV***. . . . What other company do you have or anybody has that can match this many opportunities in this year alone? Now people think they should sell shares and that's their right. But for me, double digit [stock price]. Triple digit [stock price], if we have approval for these indications, triple digits is what I indicated. . . . I'm talking about in the very near future. So that's where we are.

448. Defendant Pourhassan highlighted Defendants' purported efforts with respect to the COVID-19 long hauler indication (which went nowhere following the conclusion of the trial, *see infra*), claimed that "[w]e could be the only product" for that indication and then asked investors if they wanted to sell before that happened. Likewise, Pourhassan hyped Defendants' efforts with Health Canada for COVID-19 (which went nowhere, *see infra*), and then predicted a double or ***triple*** digit stock price on the strength of these "opportunities."

b. Hyping Interactions with the FDA

449. Defendants repeatedly told investors that the FDA's possession of the safety and/or efficacy data from CytoDyn's HIV and cancer studies and trials led the FDA to move more quickly or demand less of CytoDyn with respect to leronlimab's proposed COVID-19 indications. For instance, when asked by Proactive Investors "[h]ow it is possible that you're

skipping to phase 2 efficacy trials" in COVID-19, Defendant Pourhassan touted the HIV safety results, speculating that "with that kind of data for [] safety that FDA possessed from us, they always give us phase two very quickly . . . . based upon all the data that we have gathered in the past." Pourhassan also touted the Company's "very big start . . . with the FDA," which Pourhassan claimed was due CytoDyn's treatment of "over 840 [HIV] patients with zero serious adverse events attributed to [leronlimab]" and leronlimab's purported lack of "toxicity or side effects." Similarly, Defendant Pourhassan intimated that the agency "saw that there is something" in the data which led the FDA "to expedite[] our Phase II immediately."

450. Defendant Pourhassan also claimed that information from CytoDyn's March and April 2020 eIND patients had an impact on the FDA. For instance, during a Proactive Investors interview, Pourhassan touted the eIND results as "really, really amazing," claiming that before these results, CytoDyn was "not given a green light from the FDA to go to [a] phase two [trial] because . . . we didn't have any animal[studies]," but "when the first one of those two [New York-based COVID-19] patents self extubated . . . that started to make the FDA feel more relaxed," such that the regulator agreed to the Phase 2 and Phase 2b/3 Trials.

451. Defendants also implied or, in certain instances stated explicitly, that the FDA was actively supporting CytoDyn's efforts with respect to COVID-19. For instance, CytoDyn issued a press release claiming that the FDA had asked the Company to file the Phase 2b/3 Trial (CD12) protocol. Pourhassan also claimed that the FDA requested CytoDyn's interim analysis from the Phase 2b/3 Trial [CD12) and provided guidance with respect to an "open-label extension" for the same trial. Likewise, Defendant Pourhassan claimed that "[o]nce again, the FDA continues to be very supportive of everyone's efforts to increase access to leronlimab." Defendant Pourhassan further touted the "green light" CytoDyn had received from the FDA with respect to the Phase 2b/3 Trial (CD12) as "a major milestone," stating that he was "very happy that the FDA has worked with us so quickly and able to expedite this since there was some positive results." Pourhassan also stated, "[w]hen 200 companies run to [the FDA and] say, 'hey,

we got the solution to coronavirus! Please say something positive so our stock can go up,'" the FDA "get[s] worried" but "they have given us everything we have asked for."

452. Later, in response to a question about the FDA's apparent reluctance "to realize how many lives can be saved by using leronlimab," Pourhassan replied, "please don't point fingers at [the U.S.] FDA at the time that they're doing a fantastic job separating two hundred companies from the real to fiction. ***Obviously, they believe that we have something here***. That's why they've been giving us Phase 2 and Phase 3 . . . and emergency IND approvals left and right . . . one after another." On several occasions, Pourhassan stated that CytoDyn "should be able to get approval" from the FDA to use leronlimab to treat COVID-19. After CytoDyn submitted its top-line report for the Phase 2 Trial (CD10) to the FDA and requested an EUA, Pourhassan stated during a Proactive Investors interview, "we [] look forward to surpris[ing] everybody . . . wh[en] we g[e]t . . . emergency use authorization" in the U.K. or the U.S.

453. Based upon these statements, CytoDyn's paid promotional outlets speculated about further actions the FDA would take with respect to the use of leronlimab to treat COVID-19. For example, an Emerging Growth report speculated that the FDA could upgrade CytoDyn's requested Phase 2 trial "to a phase 3 trial," concluding that "[t]he science supports a COVID-19 approval." Still another Emerging Growth reporting claimed that "[t]he FDA has sent a very strong signal that approval is weeks away. There is a chance it could take longer, but given the incredibly weak data that won remdesivir an FDA emergency approval it's reasonable to think that this is a shoe in." A further Emerging Growth report claimed that "FDA approval in COVID-19 is expected early next year [2021] and they are very close to an EUA from the Philippines, the United Kingdom, and the United States."

454. Ultimately, the FDA (i) made clear that it had not made any determinations of the safety or efficacy of leronlimab for ***any*** indication, (ii) rejected CytoDyn's requested EUA for mild-to-moderate COVID-19 patients, and, critically, (iii) determined that the clinical data available did not support the clinical benefit of leronlimab for the treatment of COVID-19.

c. Hyping COVID-19 Trials/Indications

455. **Childhood Inflammatory Disease from COVID-19**. Defendants discussed the use of leronlimab to treat childhood inflammatory disease from COVID-19 during a May 13, 2020 Wall Street Reporter Next Super Stock livestream. Thereafter, on May 15, 2020, CytoDyn issued a press release announcing that it was offering "no-cost exploratory laboratory testing for childhood inflammatory disease associated with COVID-19" through IncellDx. During a June 2, 2020 Wall Street Reporter Next Super Stock livestream, Defendant Pourhassan stated, "[o]ther trials we are thinking about is the COVID-19 for children[.] That is going forward." No such trial has occurred.

456. **COVID-19 Long Haulers.** Defendant Pourhassan raised the possibility of a long hauler study on August 12, 2020, stating "[w]e are thinking about getting involved in a long hauler study . . . . We [] have centers that have reached out to us and they want to do this study." Defendant Pourhassan claimed during a September 16, 2020 conference call, "there is no medication for this population and we have some very exciting data generated that is absolutely powerful." Defendant Kelly likewise stated, "[w]e believe th[e COVID-19 long-hauler data] is a potential game changer for CytoDyn for CytoDyn shareholders and patients."

457. Defendants updated investors about the COVID-19 long hauler indication during CytoDyn's November 5, 2020 conference call. Thereafter, on November 17, 2020, CytoDyn announced that it had filed a protocol for a phase 2 clinical trial for "long-hauler" COVID-19 patients, confirming in another press release on November 23, 2020, that CytoDyn was "in full swing to . . . initiate our Phase 2 trial" for COVID-19 long-haulers "and perhaps complete enrollment in 4-6 weeks."

458. On June 21, 2021, CytoDyn announced the top-line results for its COVID-19 long-hauler trial. According to CytoDyn's COO and Head of Clinical Development, Chris Recknor, M.D., although the COVID-19 long-hauler "study was not designed to show statistically significant differences due to the small sample size of 56 patients, clinically

meaningful improvements in leronlimab over placebo were observed." Defendant Pourhassan further stated, "[p]rior to the commencement of this trial, the FDA advised us that our long-haulers trial is considered an exploratory trial; thus, a follow-on trial will be necessary prior to potential approval. Our hope . . . is that the [FDA] will grant us a Breakthrough Therapy designation and provide guidance for a Phase 3 trial protocol."

459. To date, CytoDyn has neither applied for nor received a Breakthrough Therapy designation for COVID-19 long haulers and CytoDyn has not completed any further trials for this indication.

460. **Phase 3 Trial for Mild-to-Moderate COVID-19 patients**. Following their receipt of disappointing Phase 2 Trial (CD10) results, Defendants claimed to be working on a Phase 3 Trial for mild-to-moderate COVID-19 patients. For example, during a September 23, 2020 Dr. Been interview, Defendant Pourhassan stated, "[w]e build on that a Phase 3, which is COVID-19 patients for moderate. So we're in the mix of going with Phase 3. We asked FDA and FDA said, 'let's talk'. So we're working on that. So that awarded us a path to an approval for mild-to-moderate patients." Later during the same interview he stated, "[n]ow we know exactly how many patients to enroll in the moderate Phase 3, we know exactly which primary endpoint to go after to be able to assure success, and we can enroll that, this year most likely, and be able to go forward with it." No such trial was ever completed by CytoDyn in the U.S.

d. Hyping Operation Warp Speed

461. As early as April 2020, Defendants hyped the idea of CytoDyn receiving COVID-19 related government funding. During an April 27, 2020 call, a participant asked for "an update" on Pourhassan's assertion that "CytoDyn will apply for government grants for leronlimab as a treatment for COVID-19." Pourhassan respond, "I can tell you that that's going forward. Dr. Scott Kelly is taking care of those applications that we were given a green light by the government agencies saying that 'we wanted to see your application,' and we are interested in funding." Pourhassan further confirmed that "Dr. Bruce Patterson has been very much

involved in that, but we will update everybody hopefully very soon," and noted the potential government funding was "another reason that I am not raising funds very quickly." Pourhassan reiterated these statements during a May 1, 2020 presentation: "[w]e don't have anything that give us green light to receive funding," he stated, "but its very, very positive."

462. Then, on August 21, 2020, Dr. Patterson appeared on a webisode of Dr. Drew Pinsky's Dose of Dr. Drew. During the show, Dr. Drew asked if "Operation Warp Speed [was] aware of leronlimab?" to which Dr. Patterson responded, "[t]hey are . . . CytoDyn received a email, I received the email from Operation Warp Speed, so yes, they are aware of it [leronlimab]. And I think we'll move forward with them [Operation Warp Speed]." Posted on YouTube, Dr. Patterson's statement quickly went viral, with "[i]nvestors who closely follow the company shar[ing] it on social media and message boards, including Investors Hub, a forum popular with penny-stock traders." Following Dr. Patterson's assertion that OWS was not only aware of leronlimab but that CytoDyn was planning to "move forward with them," the price of CytoDyn's common stock and trading volume increased 13% and 164%, respectively, at the close of trading on August 21, 2020, and the stock price increased another 12% at the close of the next trading day, August 24, 2020, for a two day price increase of 25%. In an August 26, 2020 article discussing the incident, the *Wall Street Journal* wrote, "[t]he market for small biotechs working on coronavirus treatments is so hot that sometimes all it takes is a whisper to send a stock soaring."

463. However, as was so often the case with Defendants' promotional efforts concerning COVID-19, CytoDyn was not, in fact, being considered for inclusion in the Operation Warp Speed program. A senior administration official confirmed to the Wall Street Journal that "CytoDyn had only completed a preliminary qualification for being included in the initiative" and "submitted information through a so-called CoronaWatch, a program run by the Biomedical Advanced Research and Development Authority, or Barda, to assess the viability of drugs and therapeutics that might be effective against COVID-19." According to the same

administration official, "[t]echnical experts reviewed the submission and opted not to proceed further at this time." Critically, the *Wall Street Journal* reported that "[t]he team responsible for reviewing the materials makes clear to companies that submissions are for informational purposes only and don't lead to funding on their own. . . . Companies must apply to specific grant programs to receive funding . . . which CytoDyn hasn't done at this time."

e. Hyping Non-U.S. Licensing, Distribution, and Regulatory Efforts

464. **China, Taiwan, and South Korea**. On February 12, 2020, CytoDyn issued a press release announcing that it had signed a "nonbinding letter of intent (LOI) for the joint development and licensing of leronlimab in China with Longen China Group." During a Wall Street Reporter February 24, 2020 interview, Pourhassan confirmed that the "Longen Group" "is working with us right now to get" COVID-19 patients treated with leronlimab. Pourhassan further stated that CytoDyn was working on another unspecified letter of intent and term sheet and had been "approached . . . by other countries which we will be announcing very soon our agreement with them." Later in the interview, Pourhassan claimed that "we are now in talks with South Korea, Taiwan, [and] China." Defendant Pourhassan and Dr. Patterson reiterated these statements on March 5, 2020.

465. However, by April 2020, CytoDyn had moved on from its much-hyped nonbinding LOI with Longen. As Defendant Pourhassan explained on April 17, 2020, "[w]e ***were*** in talk[s] with a company called Longen, and as we got other companies involved, we moved to the different companies." During the same call, Pourhassan also confirmed that CytoDyn wouldn't be moving forward with talks Taiwan: "We also talk about Taiwan, ***we didn't move forward on that either***." But the hype machine continued. As to those "different companies," none of which Defendants named (or has since named), Pourhassan stated, "there are two companies in China right now that are very close to making some [term] sheets, some nonbinding [term] sheet presentation to us. We are very happy with those two. We're going

forward." To date, CytoDyn has not executed any agreements with any companies in China with respect to joint development or licensing of leronlimab in China, South Korea, or Taiwan.

466. **Health Canada**. Defendants' promotional efforts with respect to Cytodyn's application under Health Canada's Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 ("Interim Order") are another example of "[p]ress releases or promotional activity announcing events that ultimately do not happen" and is indicative of Defendants' fraudulent efforts to pump up the price of CytoDyn common stock after the disappointing leronlimab COVID-19 trial results.

467. In this instance, on April 8, 2021, Pourhassan claimed that CytoDyn "will be submitting . . . all the packages that we need to send to [Health Canada]" by April 15, 2021 and concluded that "once we finish giving that interim order package when its complete and if we commit ourselves to do a trial over there, we can start selling this business" in Canada. On April 19, 2021, the Company issued a press release announcing that it had submitted just "the manufacturing section (CMC)," which it described as the "[m]ost [c]rucial [s]ection" of its Interim Order Application, and stated that it "anticipate[d] the remaining sections will be submitted in the very near future."

468. By July 2021, CytoDyn had not announced anything with respect to its Health Canada Interim Order application. That is because CytoDyn had failed to complete its application. According to the Health Canada website, on March 21, 2021, CytoDyn filed with Health Canada an application under section 3 of the Interim Order "to obtain market authorization for leronlimab as a treatment for patients with severe or critical COVID-19." The website confirms that CytoDyn "had submitted drug quality and non-clinical components" but, on June 15, 2021, "indicated that the clinical package"—the data that showed that leronlimab actually treated COVID-19—"would be available December 15, 2021." Health Canada closed CytoDyn's leronlimab application on September 16, 2021, without a decision because the Interim Order had expired. Health Canada's webpage notes that "[a]t the time of the closure,

formal review of the clinical package had not begun because it was not available," "[t]here are no approved clinical trials underway in Canada for the use of leronlimab in the treatment of COVID-19," and "[a] New Drug Submission under the Food and Drug Regulations was not filed by the [applicant]."

469. **U.K. MHRA**. On April 7, 2020, CytoDyn announced that it was "collaborating with U.K.'s Department of Health to provide emergency access to leronlimab for severe and critically ill COVID-19 patients." On April 17, 2020, Defendant Pourhassan stated, "all of our data for United Kingdom is ready to move forward," and "there is a special program that we can get in front of the Chief Medical Officer, [U.K.] with our data and protocol, . . . [s]o hopefully, by Monday, they will have everything. And by next week, it will be in front of the Chief Medical Officer of [U.K.] and they are giving approval, some limited approval for the product . . . we have a very good chance of that because our data is very nice. So we could have some very nice pleasantly surprised next week from [U.K.]" And, "next week with the United Kingdom, I'm really excited to see what happens with that . . . I think they'll give us a special approval on that." On April 27, 2020, Pourhassan stated, "in regard to UK, we have already started the process of getting Compassionate Use Agreement and probably having our trial in road in the United Kingdom."

470. In an August 17, 2020 press release, CytoDyn claimed that it "hope[d] to obtain emergency use approval from the MHRA in the U.K." Two days later, on August 19, 2020, CytoDyn issued a press release claiming that it had "provided its Top-line Report from its recently completed Phase 2 [COVID-19] clinical trial . . . to Medicines and Healthcare Products Regulatory Agency (MHRA)" and "requested the regulatory pathway for Fast Track approval noting the efficacy and safety results from the Phase 2 trial." The next day, August 20, 2020, CytoDyn issued another press release, this time announcing that after "several months" review of leronlimab manufacturing and safety data, the U.K. MHRA had authorized the Company to "enroll for its ongoing Phase 3 COVID-19 trial" in the U.K. Pourhassan stated, "We are very

pleased with the MHRA's confidence in leronlimab to initiate enrollment of patients in the U.K. for our current CD12 protocol."

471. In reality, by November 2020—one month before the trial was estimated to be completed—there were no U.K. trial locations listed for the Phase 2b/3 Trial (CD12). To date, CytoDyn has no active COVID-19 trials in the U.K. and the U.K. MHRA has not been approved or authorized the marketing and sale of leronlimab for COVID-19.

f. Hyping NASDAQ Uplisting

472. Defendants' efforts to uplist CytoDyn's common stock to the NASDAQ exchange is another example of promotional activity related to an event that did not happen. This particular "red flag" is important because Defendants used the NASDAQ uplisting thresholds, and in particular the $3.00 and $4.00 stock price requirements and investors' desire to see the Company trade on the NASDAQ to further their stock promotion fraud.

473. Defendants first raised uplisting to a national exchange before the Class Period, but continued frequently hyping the possibility of uplisting to the NASDAQ exchange during the Class Period. After CytoDyn's stock price reached unprecedented heights in June 2020, Defendants announced that CytoDyn had completed and submitted its multi-part application for the NASDAQ exchange on July 15, 2020.

474. At the time, Defendants represented that CytoDyn satisfied the NASDAQ listing requirements. In particular, Defendants focused on the stock price criteria, with Defendant Pourhassan noting during a July 4, 2020 Dr. Been interview that "we now have a price that can qualify us for NASDAQ." In a later interview, Pourhassan further explained "[w]hy [uplist] now? . . . we think everything is coming together in a beautiful way for us. We wanted to have the stock to go to a different level with all this stuff that we have. I mean, it's rightfully so. . . . Things are happening in a spectacular way now. And to put the finishing touches is uplist to the NASDAQ."

475. Likewise, during a July 13, 2020 call with investors, Defendant Mulholland stated: "First of all, I'd say that we meet—we have no issues on the other standards. And if we look at the stock price, if at the time of uplist, the stock is at 4 dollars, we're fine. If by chance, the stock should soften a bit to less than 4, down to say 3 dollars or above, we're still okay, we're still fine, because we meet the net tangible assets standard. So, we're in good shape."

476. Defendant Pourhassan also claimed that the NASDAQ might relax its requirements due to the COVID-19 pandemic. For instance, during a July 4, 2020 Dr. Been interview, Pourhassan stated: "I said, 'Michael Mulholland has something up his sleeve'—that there is a shortcut always in getting to uplisting. At the time, the price of the stock wasn't at the price that it is—it was much lower I believe. And that is to allow us not to raise money before uplisting and we are waiting to see if that would be accepted. Especially with the special situation with [a] pandemic requires special actions, and we are asking to hopefully not to have to—for us not to meet the funding requirement of uplisting. So we're waiting for that right now."

477. In addition to discussing the criteria, Defendants also initially claimed that the NASDAQ uplisting process would be a four to six week process. By the end of August 2020, or six weeks after CytoDyn had filed its application, CytoDyn was still trading on OTC. During a September 23, 2020 Dr. Been interview—10 weeks after CytoDyn filed its applicaton—Defendant Pourhassan stated, "[t]he exchange told us that they are ready to give us our final answer . . . and we are hoping to get that answer either tomorrow or the day after tomorrow. That's what the exchange told us."

478. Eleven weeks later, and over four months after CytoDyn had filed its application, the Company's common stock was still trading OTC. Defendant Mulholland provided an update on December 10, 2020:

> I'd first like to confirm that our application has not been rejected. We are on hold. Why? Very simple . . . [u]ntil we have met net income, there are 2 standards potentially applicable to CytoDyn. First, the equity standard or the market value of listed securities standard. Of the 9 requirements described for each standard, our focus is on 3 requirements under the equity standard . . . positive

> stockholders' equity of $5 million, . . . [a] bid price of $4 a share or a closing price of $3 a share, . . . [and] net tangible assets of more than $2 million.

479. According to Mulholland, as of "8/31, we were a positive $2.7 million" shareholders' equity, "we're not at $4 [per share bid price], but we are over $3 [per share closing price]," and for "the August 31 quarter, our net tangible assets was a negative $10.2 million." Per Mulholland, "these shortfalls are curable" and "the final decision still rests with the exchange."

480. One month later, with CytoDyn still trading OTC, Defendant Pourhassan claimed during a January 6, 2021 investor call that "hopefully, we will be uplisting . . . soon," and stated: "Mike Mulholland spoke to NASDAQ just a couple of days ago. I just want to make sure everyone know that we are in touch with them. They have given us some optimism that we can go forward and hope that we will be uplisted. . . . And I'm very optimistic that we could get to uplist as soon as we hear the next step from NASDAQ."

481. Two months later, following the stock price decline in response to the negative Phase 2b/3 Trial (CD12) results led to a decline in CytoDyn's shares below the NASDAQ $3.00 closing price threshold, Defendant Mulholland stated, "[w]e believe an approval is near." However, to date, CytoDyn has not, in fact, uplisted to the NASDAQ and continues to trade OTC.

2. Red Flag: CytoDyn Has Repeatedly Increased the Number of Authorized Shares without a Meaningful Increase in Total Current Assets

482. There has been a substantial increase in the authorized shares since 2018 without any meaningful increase in total current assets. As an initial matter, in November 1, 2017, the CytoDyn Board of Directors proposed and shareholders approved a proposal to effect a reverse stock split and a simultaneous reduction in the total number of authorized shares of common stock to 200,000,000 shares before August 24, 2018. That split and share reduction did not occur and, instead, CytoDyn's Board of Directors changed course and has proposed (and the shareholders have approved) successive material increases in authorized shares from

375,000,000 to 450,000,000 authorized shares on June 7, 2018, to 600,000,000 authorized shares on November 8, 2018, to 700,000,000 authorized shares on May 22, 2019, to 800,000,000 authorized shares on June 22, 2020, and to 1,000,000,000 authorized shares on November 24, 2021.

483. At the same time, CytoDyn's total current assets have not meaningfully increased. The chart below reflects the authorized share increase, and, separately, total current assets and inventory or net inventory, and the calculation of total current assets less inventory or net inventory, as of the date of the authorized share increase. For the reasons discussed below, the more appropriate comparison is the authorized share increases to the total current assets without inventory or net inventory.

Share Increase Date	Authorized Share Increase	Total Current Assets	Inventory or Net Inventory	Total Current Assets w/o Inventory
6/7/2018	75,000,000	$3,320,627[19]	$0	$3,320,627
11/8/2018	150,000,000	$7,539,780[20]	$0	$7,539,780
5/22/2019	100,000,000	$4,467,471[21]	$0	$20,427,545
7/22/2020	100,000,000	$36,827,032[22]	$19,146,678	$17,680,354
11/24/2021	200,000,000	$102,786,000[23]	$91,558,000	$11,228,000

484. This is because CytoDyn only was able to recognize inventory or net inventory as assets by capitalizing its inventories procured or produced in preparation for product launches based on management's determination that FDA approval of leronlimab was "probable" as of

[19] As of May 31, 2018.

[20] As of August 31, 2018.

[21] As of February 28, 2019.

[22] As of May 31, 2020.

[23] As of August 31, 2021.

February 29, 2020. The SEC raised this issue in correspondence with CytoDyn's management (including Defendant Mulholland) in the context of the Company's proposed Form 10-K for FY20. In particular, the SEC did not believe that CytoDyn had provided "a sufficient basis to support management's assertion that prelaunch inventory represented an asset at each date it was capitalized" because, among other things, the FDA had not yet performed a substantive review of leronlimab's safety and efficacy and CytoDyn had not yet resubmitted its HIV BLA following the FDA's RTF letter (and has not yet completed resubmitting its HIV BLA as of the date of this Complaint). The SEC asked CytoDyn's management to "reconsider the appropriateness of its capitalization conclusion in light of" these issues.

485. Ultimately, the SEC required CytoDyn to "expand [] proposed disclosures to clarify that, due to th[e] RTF letter, the FDA has not yet commenced their review of [the Company's] BLA, including leronlimab's safety and efficacy" and "discuss and update the risks and uncertainties surrounding market acceptance and salability of leronlimab in [the Company's] future periodic reports." Given the SEC's concerns with the accounting for CytoDyn's inventories as assets, and the fact that the Company's inventories make up a substantial portion of the increase in total current assets in 2020, it is more appropriate to compare the authorized share increases to the total current assets at the time the increases were authorized less inventory or net inventory amounts.

3. Red Flag: CytoDyn Retained at Least 12 Entities to Promote the Company's Common Stock During the Class Period

486. According to the SEC, "[f]raudsters may promote a stock in seemingly independent and unbiased sources," including in internet forums, social media, and investment newsletters and reports." In a series of Investor Alerts, the SEC has identified how stock promotion services or outlets could be "used to carry out schemes designed to deceive investors," including through "[t]outing" or "promoting a stock without properly disclosing compensation received for promoting the stock," "'[p]ump and dump' schemes," and

"[u]ndisclosed conflicts of interest," or "falsely claiming to provide independent analysis or failing to explain conflicts of interest (or biases), including financial incentives, that may influence the investment recommendations." With respect to the concept of "touting," the SEC explained that while it was not illegal as long as the stock promotion services or outlets "disclose who paid them, how much they're getting paid, and the form of the payment, usually cash or stock," but the SEC warned, "fraudsters often lie about the payments they receive and their track records in recommending stocks."

487. Prior to and during the Class Period, CytoDyn engaged "third party providers . . . to provide investor relations services, public relations services, marketing, brand awareness, consulting, stock promotion, or any other related services to the Company." CytoDyn filed regular certifications with the OTCQB purportedly containing "a complete list" of these providers "from the Company's prior fiscal year end to the date of th[e] OTCQB Certification." As the Company's CFO, Defendant Mulholland executed two of three certifications that cover the Class Period.

488. Across the relevant certifications, CytoDyn has identified the following entities and individuals: (i) RedChip Companies; (ii) Proactive Investors; (iii) Global Discovery Group (aka Emerging Growth); (iv) Resources Unlimited (including Michael Sheikh who was separately listed on earlier certifications); (v) LifeSci Public Relations; (vi) Edison Investment Research Inc.; (vii) Marek Cizsewski; (viii) Michael Elliot dba CEO Live (aka CEORoadshow.com); (ix) MoneyTV; (x) Wall Street Reporter; (xi) Shift Media Lab; (xii) Results Media Inc.; (xiii) Stock Day Media; and (xiv) Stir-Communications, LLC.

489. In its relevant certifications, CytoDyn listed "brand awareness" next to the names of six entities. These entities included Proactive Investors, MoneyTV, Wall Street Reporter, Shift Media Lab, Results Media Inc., and Stock Day Media. Other than its stock, the only "brand" for which Defendants may have sought awareness was leronlimab, although CytoDyn did not have approvel to market or sell leronlimab for any indication. None of these entities, however,

identified as their target audience members of the medical professional or pharmaceutical communities. Instead, these entities' target audience was investors and the "brands" they pitched were microcap stocks like CytoDyn. For instance, Proactive Investors stated that it "enable[d] companies and investors to connect intelligently . . . providing breaking news, commentary and analysis on hundreds of listed companies." Wall Street Reporters described its "[m]ission" or "purpose" as "help[ing] investors worldwide discover profitable trading and investing ideas." Stock Day Media "provides companies with customized solutions to their news distribution" and claims to be "the fastest growing media outlet for Nano-Cap and Micro-Cap companies," "educat[ing] investors while simultaneously working with penny stock and OTC companies," and purportedly "providing transparency and clarification of under-valued, under-sold Micro-Cap stocks of the market."

490. Additionally, these certifications list ***six*** separate companies each of which CytoDyn claimed provided consulting and/or investor relations services. These companies included Red Chip Companies, Global Discovery Group (aka Emerging Growth), Resources Unlimited, Edison Investment Research Inc., Marek Ciszewski, and Michael Elliot dba CEO Live (aka CEORoadshow.com). While not identified by CytoDyn as providing "brand awareness" services, many of these entities did purport to connect companies like CytoDyn with retail investors. For example, Global Discovery Group (aka Emerging Growth) provided "[s]tock [m]arketing" services, including "creative media campaigns" that "target the shareholders of your blue chip public company peers." Red Chip Companies purported to be "the world leader in investor relations, financial media, and research for microcap and small-cap stocks" helping "companies achieve their capital markets goals" by combining "traditional investor relations services with multi-media marketing." Resources Unlimited claimed to be "a full service investor relations firm for companies that trade on the [OTC] [m]arket, aka 'penny stocks'" helping "executives to deliver their story to the investment community" and "putting [their] company in the investor spotlight." Michael Elliot dba CEO Live (aka CEORoadshow.com)

touted itself as "the leading Investor Relations industry portal that introduces public companies to thousands of active investors, fund managers, and financial institutions," and "help companies" that "[h]ave little or no Wall Street interest and activity," "[n]eed a retail investor base," or "[w]ant to forge deeper relationships with retail investors."

491. These certifications also may not be complete. For instance, at least two websites that disclose some compensation by companies featured thereon, posted research reports and/or articles about CytoDyn during 2020-2021, MN1 and Zero Hedge.

492. All in, CytoDyn compensated at least 12 separate entities for "brand awareness," "consulting," and/or "investor relations," during the Class Period. On information and belief, and as set forth in detail above (*see* Section III.C), these entities contributed to Defendants' promotional efforts that were part and parcel of their stock promotion fraud.

493. The SEC has also warned investors that "[w]hen you read an article on an investment research website, be aware that the article may not be objective and independent" because, "[f]or example, the writer may have been paid directly or indirectly by a company to promote that company's stock" and "fraudsters may generate articles promoting a company's stock to drive up the stock price and to profit at your expense." The SEC likewise identified red flags indicating that the stock promotion services or outlets are being used to engage in fraud, including non-existent, vague, or buried disclosures, and articles or reports aggressively promoting the company's stock price, promising investors a high rate of return on their investment, and suggesting that there is a limited window for the investor to purchase the security.

494. Emerging Growth is one example of a promotional outlet that had non-existent, vague, or buried disclosures with respect to CytoDyn articles or reports. For instance, between December 4, 2019 and April 30, 2020, Emerging Growth reissued CytoDyn's press releases verbatim on its website listing the author as "EG Staff," with the tagline, EG "a leading independent small cap media portal with an extensive history of providing unparalleled content

for the Emerging Growth markets and companies, reports on CytoDyn." Additionally, between March 23, 2019 and May 21, 2021, Emerging Growth issued more than 15 reports featuring analysis and "[i]nvestment [s]ummar[ies]," authored by "admin" or, later, contributor "Chris Long."

495. While it appears that CytoDyn engaged Global Discovery Group (aka Emerging Growth) during this period, Emerging Growth's disclosures of such payment are non-existent, vague, or buried. As an initial matter, ***no specific*** disclosures or referral to Emerging Growth's disclosures accompanied the "reports" authored by Chris Long. Some reports authored by Emerging Growth "admin" referred investors to Emerging Growth's disclosures. While Emerging Growth's disclosures stated that "Companies profiled on EmergingGrowth.com have paid EG a minimum of $500.00 for each post," these disclosures failed to identify the companies that had paid, the amount, or the type of payment (e.g., beyond the $500.00 per post). Moreover, Emerging Growth's disclosures claimed that "any and all compensation that has been received by or for a profiled company . . . will be detailed under its own disclosure on the page where the article or story about that company appears." Critically, Emerging Growth reports authored by "admin" beginning with the May 8, 2020 report did not contain this information with respect to CytoDyn.

496. Additionally, the articles authored by "EG Staff" and the reports authored by "admin" before May 8, 2020, do contain a CytoDyn specific disclosure, explaining that the posts "is not without bias . . . EmergingGrowth.com has been compensated by or for a company or companies discussed in this article" and referencing payments from CytoDyn of $7,500 through the April 30, 2020 and stating that Emerging Growth "may or may not receive additional compensation, details about which can be found in our full disclosure." These articles and reports linked to a CytoDyn specific "full disclosure" webpage that stated "EG has received [$12,500] and EG can receive an additional [$17,500] in consideration for its work with CytoDyn, Inc."

497. As a result of Emerging Growth's non-existent, vague, and buried disclosures it is impossible to determine with any certainty what CytoDyn paid to Emerging Growth and for which articles or reports about CytoDyn that Emerging Growth posted on its webpage.

498. Further, just before and during the Class Period promotional outlets compensated by CytoDyn posted articles or reports that aggressively promoted the Company's common stock, intimated that investors would have a high rate of return on any investment in CytoDyn common stock, and suggesting that there was a limited window in which the investor could purchase CytoDyn common stock and achieve that high rate of return.

499. For example, the "Investment Summary" section of a February 10, 2020 Emerging Growth report stated:

> CYDY has a tremendous amount of potential to be the next Gilead (GILD). They have a platform drug with 32 indications. The have filed for one BTD but then potentially have another in the works. Having two shots on goal for a BTD is like having 2 shots at $8 billion which is the average market cap of a BTD stock. With the new patient data it appears like they are a definitive path toward regulatory approval in the coming weeks or months. This could be the best lottery ticket you will ever buy. The drawing is in the next two months.

500. Likewise, the "Investment Summary" of a March 23, 2020 Emerging Growth report stated:

> Despite its very quick drug development CYDY investors just haven't been quick to grasp the ramifications of an approval in COVID-19. An approval would mean jumpstarting sales all across the globe. **The science supports a COVID-19 approval**. So investors with an appetite for risk should be bidding the stock up in anticipation of these compassionate use trial results. If the patients live or even get discharged from the hospital there could be much fanfare. Everyone knows that Trump likes to have winners and CYDY might make it to the podium within the next week because they have been very transparent in their reporting efforts.

(Emphasis in original.)

501. Additionally, the "Investment Summary" of a June 12, 2020 Emerging Growth report stated:

> It's astonishing how undervalued this stock seems to be. In the conference call Dr. Pourhassan said in his opinion the stock is "way way undervalued." Hundreds of thousands of people have died from COVID-19 and if the masses found out there was a drug that was non-toxic and returned homeostasis of the immune system the

> social outcry alone would get the drug approval. The FDA has sent a very strong signal that approval is weeks away. There is a chance it could take longer, but given the incredibly weak data that won remdesivir an FDA emergency approval it's reasonable to think that this is a shoe in. With close to $12 billion in revenues likely in the next 1.5 years investors need to ask why the stock is trading at a 90% discount to just one times sales. Simple, people need to stop listening to AF and his meaningless drivel and look at the facts. If AF continues to attack CYDY he will go down as the biggest stooge on the planet. This is in pole position to be the first FDA approved drug to treat COVID-19.

502. Further, the "Investment Summary" of a July 30, 2020 Emerging Growth report stated:

> There's a lot of data swirling around and it's settling down to whether or not leronlimab is going to meet its primary endpoint. If the 64% reduction in SAE's doesn't sway investors, then perhaps the anecdotal survival data on over 60 compassionate use patients who should have died. What about the UCLA study that showed the average time of hospitalization was 5 days on compassionate use patients. Compare that to Gilead Sciences (NADSAQ: GILD) mild to moderate results detailed in the NEJM remdesivir study that shortened hospital stays from 15 to 11. Investors should be able to figure out that 5 days is much better than 11 but sadly they haven't which is why the stock isn't trading significantly higher. One institutional investor that did the offering yesterday gets it, and he made a $25 million bet on it. Investors can continue to drink the Adam Feuerstein Kool Aide that this is a smoke and mirror show, but the reality is that leronlimab is saving lives and the genie is out of the bottle. . . .The path toward leronlimab meeting its endpoint is clear, and investors have two choices. They can completely discount all this anecdotal evidence that the drug works, and wait for efficacy results or realize how likely approval is and buy before the announcement and make an extraordinary return versus a good return.

503. Likewise, in a December 8, 2020 Emerging Growth report, the "Investment Summary" stated:

> CYDY on the other hand seems to have a lot more going for it. . . . Many investors are expecting the severe to critical clinical trial to be completed in the next couple of weeks. This could be a major catalyst as investors flock back into this name for fear of missing a runaway freight train that may be the next drug to not only get and EUA but all get full marketing approval. . . . .The CEO of CytoDyn had indicated that COVID-19 sales could top $7 billion next year. Based on 1 times COVID sales that works out to a $12.00+ stock price and represent a 5x return in the short term. CYDY is quite undervalued and given the very strong correlation of EUA approved drugs that make it to this list it should be aggressively purchased going into the shareholder update.

4. Red Flag: Despite CytoDyn's Lack of Operational Success Defendants Still Project Large Future Revenues

504. Where a company has no history of operational success, like CytoDyn, the projection of large future revenues is a red flag of fraud, especially if those projections appear to be based solely on information about the company's industry rather than the company itself.

505. As noted above, Defendants touted billions of dollars in potential revenues from the sale of leronlimab during the Class Period, despite the fact that CytoDyn did not have a saleable product, did not yet have FDA (or indeed any regulatory agency) approval of leronlimab for any indication, and had yet to recognize any material revenues in its 18 years of existence as a public company. Moreover, the numbers that Defendants and CytoDyn's paid promotional outlets touted were based solely on the market or pricing for competitor drugs.

506. For example, during a November 11, 2020 Proactive Investors interview, Defendant Pourhassan stated: "we have manufactured successfully 1.2 million vials this year and about 3 to 4 million [for] next year. . . . When we get our emergency use authorization . . . then all we have to do is sell these [vials] at the same price that is being COVID-19 therapies are being sold. That's about $2 billion this year and about $5 billion dollars." Pourhassan made similar statements on December 10, 2020, and forecasted FY2021 revenues of "$5 to $10 billion." Likewise, with respect to future leronlimab sales, a June 12, 2020 Emerging Growth report stated that CytoDyn "expects to produce 1.5 million vials of leronlimab in the next half of 2020 for 375,000 patients," "generat[ing] $2.5 billion in sales this year," and "an estimated 6 million vials" for "$9.0 billion in revenue" in 2021 "if leronlimab receives regulatory approval."

VIII. INDIVIDUAL DEFENDANTS ENGAGED IN INSIDER TRADING IN VIOLATION OF SECTION 20A

507. As discussed above, throughout the Class Period, Defendants Pourhassan, Mulholland, and Kelly each were in possession of material, non-public information ("MNPI") regarding the Company, including about the nature, extent, and revenue impact of extensive,

undisclosed regulatory and product issues regarding leronlimab. By April 27, 2020, Defendants knew that the HIV BLA had been submitted (and resubmitted on May 11, 2020) despite the fact that it lacked critical information necessary for it to be accepted and reviewed by the FDA. Similarly, the Individual Defendants knew that the data CytoDyn possessed did not support the clinical benefit of leronlimab for the treatment of COVID-19 and, therefore, requests for EUA or other approval or authorization to market and sell leronlimab under the FDA (or other countries) regulation.

508. Defendants Pourhassan, Mulholland, and Kelly learned these facts and were in possession of such MNPI during the Class Period through, among other ways, their control of CytoDyn as the Company's senior executives and participation in or knowledge derived from meetings with the FDA concerning leronlimab and/or internal communications regarding leronlimab. Further, Defendants were intensely focused on the success of leronlimab, given that it was the lone source of potential revenue that the Company possessed. Thus, they repeatedly spoke to investors about topics specific to leronlimab and the FDA. Indeed, these Defendants are alleged to have made false or misleading statements (*see* Section V) and to have carried out a fraudulent scheme and course of conduct regarding the purported attributes of leronlimab (*see* Section IV.

509. During the Class Period, while in possession of the foregoing MNPI concerning CytoDyn, and contemporaneously with purchases of CytoDyn common stock by Class members Defendants Pourhassan, Kelly, and Mulholland traded as set forth below.

510. Defendant Pourhassan disposed of his personally held shares of CytoDyn common stock on the following dates: **April 30, 2020** (2,219,837 shares at a value of $7,838,688.41); **May 4, 2020** (1,201,652 shares at a value of $3,353,089.74); and **July 31, 2020** (156,570 shares at a value of $778,152.90).

511. Defendant Kelly disposed of his personally held shares of CytoDyn common stock on the following date: **May 1, 2020** (1,200,000 shares at a value of $3,912,480).

512. Defendant Mulholland disposed of his personally held shares of CytoDyn common stock on the following dates: **December 17, 2020** (32,000 shares at a value of $145,673.60); **December 18, 2020** (487,002 shares at a value of $2,411,439.10); **December 21, 2020** (585,797 shares at a value of $3,269,918.85); **December 22, 2020** (245,704 shares at a value of $1,349, 848.64); **December 22, 2020** (453,997 shares at a value of $3,003,008.56); and **December 22, 2020** (12,100 shares at a value of $84,700).

513. Contemporaneously with Pourhassan's, Mulholland's, and Kelly's sales, Plaintiffs purchased shares of CytoDyn common stock at inflated prices, as reflected on their certifications filed herewith as Exhibits A-D. Certain exemplary contemporaneous purchases are as follows:

514. Lead Plaintiff Courter purchased 2,700 shares & 2,670 shares on July 29, 2020.

515. Named Plaintiff Evans purchased 525 shares on July 30, 2020, and 100 shares on August 3, 2020.

516. Named Plaintiff McGee purchased 2,200 shares on December 17, 2020 and 1,700 shares on December 22, 2020.

517. Named Plaintiff Hooper purchased 1,000 shares on May 1, 2020.

518. Upon information and belief, thousands of other Class members also purchased shares contemporaneously with the Defendants' sales identified above. As alleged in this Complaint, at the time of these Defendants' sales and the purchases by Plaintiffs and other Class members, the price of CytoDyn's common stock was artificially inflated and/or maintained by the Defendants' material misstatements and omissions and fraudulent scheme.

IX. CLASS ACTION ALLEGATIONS

519. Plaintiffs bring this action on behalf of themselves and as a class action, pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of a Class consisting of all persons and entities that, during the Class Period, purchased or otherwise acquired the publicly traded CytoDyn stock and were damaged thereby. Excluded from the Class are Defendants, members of Defendants' immediate families (as defined in 17 C.F.R. § 229.404,

Instructions (1)(a)(iii) and (1)(b)(ii)), any person, firm, trust, corporation, officer, director, or other individual or entity in which any Defendant has a controlling interest, or which is related to or affiliated with any of the Defendants, and the legal representatives, agents, affiliates, heirs, successors-in-interest, or assigns of any such excluded party.

520. The members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are at least thousands of members of the proposed Class. As of July 15, 2021, CytoDyn had approximately 632,586,877 shares of common stock issued and outstanding, owned by thousands of persons, and actively traded on the OTCQB. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Record owners and other members of the Class may be identified from records maintained by CytoDyn or its transfer agent, and may be notified of the pendency of this action by a combination of published notice and first-class mail, using the techniques and form of notice similar to that customarily used in class actions arising under the federal securities laws.

521. There is a well-defined commonality of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions that may affect individual Class members include: (a) whether Defendants' actions as alleged herein violated the federal securities laws; (b) whether Defendants' statements and/or omissions issued during the Class Period were materially false and misleading; (c) whether Defendants knew or were deliberately reckless in not knowing that their statements were false and misleading; (d) whether Defendants knowingly or with deliberately reckless disregard employed a device, scheme, or artifice to defraud or engaged in any act, practice or course of business which operated or would operate as a fraud; (e) whether and to what extent the market prices of CytoDyn publicly traded common stock were artificially inflated and/or distorted before and/or during the Class Period due to the misrepresentations

and/or omissions of material fact alleged herein; and (f) whether and to what extent Class members sustained damages as a result of the conduct alleged herein, and the appropriate measure of damages.

522. Plaintiffs' claims are typical of the claims of the other members of the Class, as all members of the Class purchased or otherwise acquired CytoDyn stock during the Class Period and similarly sustained damages as a result of Defendants' wrongful conduct as alleged herein.

523. Plaintiffs will fairly and adequately protect the interests of the members of the Class. Plaintiffs have retained counsel competent and experienced in class action securities litigation to further ensure such protection, and intend to prosecute this action vigorously. Plaintiffs have no interests that are adverse or antagonistic to those of the Class.

524. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by each individual member of the Class may be relatively small, the expense and burden of individual litigation make it impracticable for Class members to seek redress for the wrongful conduct alleged herein. Plaintiffs know of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

X. FRAUD ON THE MARKET PRESUMPTION OF RELIANCE APPLIES

525. Plaintiffs and members of the Class are entitled to rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things: (a) Defendants made public misrepresentations or failed to disclosed material facts during the Class Period; (b) the omissions and misrepresentations were material; (c) CytoDyn stock traded in an efficient market; (d) the material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of CytoDyn stock; and without knowledge of the misrepresented or omitted facts, Plaintiffs and other member of the Class purchased or otherwise acquired CytoDyn stock between the time that Defendants made material

misrepresentations and omissions and the time concealed risks materialized or the true facts were disclosed.

526. At all relevant times, the market for CytoDyn's stock was an efficient market for the following reasons, among others:

a. CytoDyn common stock was actively traded;

b. As a regulated issuer, CytoDyn filed periodic reports with the SEC;

c. CytoDyn regularly communicated with public investors via established markets communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as press releases, communications with stock promotors, and communications with financial press and similar reporting services; and

d. CytoDyn was followed by financial journalists as well as securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

527. As a result of the foregoing, the market for CytoDyn's securities promptly digested current information regarding CytoDyn from all publicly available sources and reflected such information in the prices of the stock. Under these circumstances, all purchasers of CytoDyn's securities during the Class Period suffered similar injury through their purchase of CytoDyn's securities at artificially inflated prices. The *Basic* presumption of reliance applies.

528. Plaintiffs and the putative Class are also entitled to the *Affiliated Ute* presumption of reliance due to Defendants' employment of an undisclosed device, scheme or artifice to defraud or engagement in undisclosed act(s), practice(s), or course(s) of business which operated or would operate as a fraud. Defendants had a duty to disclose any devices, schemes or artifices or acts, practices or courses of conduct that defrauded or operated (or would operate) as a fraud

on CytoDyn's investors but Defendants made no such disclosure. This information was material and would have significantly altered the total mix of information made available. Plaintiffs and investors would have wanted to know this information, and, had Plaintiffs and investors known this information, they would have avoided purchasing shares of CytoDyn common stock at the prices they traded during the Class Period, if at all.

XI. INAPPLICABILTIY OF THE STATUTORY SAFE HARBOR

529. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the materially false or misleading statements pleaded in this Complaint. Further, because the statutory safe harbor and/or bespeaks caution doctrine only is applicable to claims that are based on an untrue statement of a material fact or omission of a material fact necessary to make the statement not misleading under Section 10(b) and Rule 10b-5(b), it is not applicable to claims arising under Section 10(b) and Rule 10b-5(a & c).

530. None of the statements complained of herein under Section 10(b) and Rule 10b-5(b) was a forward-looking statement. Rather, each was a historical statement or a statement of purportedly current facts and conditions at the time such statement was made.

531. To the extent that any of the false or misleading statements complained of herein under Section 10(b) and Rule 10b-5(b) can be construed as forward-looking, any such statement was not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statement.

532. To the extent that the statutory safe harbor does apply to any forward-looking statement complained of herein under Section 10(b) and Rule 10b-5(b), Defendants are liable for any such statement because at the time such statement was made, the particular speaker actually knew that the statement was false or misleading, and/or the statement was authorized and/or approved by an executive officer of CytoDyn who actually knew that such statement was false when made.

533. Moreover, to the extent that any Defendant issued any disclosures purportedly designed to "warn" or "caution" investors of certain "risks," those disclosures were also materially false and/or misleading when made because they did not disclose that the risks that were the subject of such warnings had already materialized and/or because such Defendant had actual knowledge of existing, but undisclosed, material adverse facts that rendered such "cautionary" disclosures materially false and/or misleading.

XII. CAUSES OF ACTION

COUNT I

FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND SEC RULE 10b-5 AGAINST ALL DEFENDANTS

534. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein. This Count is brought against CytoDyn and the Individual Defendants pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(a, b, and c) promulgated thereunder, 17 C.F.R. § 240.10b-5, on behalf of Plaintiffs and all other members of the Class.

535. During the Class Period, Defendants, while in possession of material adverse, non-public information, disseminated or approved the false or misleading statements and/or omissions alleged herein, which each defendant knew or recklessly disregarded were false or misleading in that they misrepresented material facts and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. Defendants carried out a plan, scheme, and course of conduct that: (i) deceived the investing public, including Plaintiffs and other Class members, as alleged herein, regarding the intrinsic value of CytoDyn common stock; (ii) caused the price of CytoDyn common stock to be artificially inflated and/or maintained artificial inflation in the price of CytoDyn common stock; and (iii) caused Plaintiffs and other members of the Class to purchase CytoDyn common stock at artificially inflated prices that did not reflect their true value. In

furtherance of this unlawful scheme, plan, and course of conduct, CytoDyn and the Individual Defendants took the actions set forth herein while using the means and instrumentalities of interstate commerce and the facilities of the OTC Market's OTCQB Venture Market.

536. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, in that they, individually and in concert, directly and indirectly, knowingly and/or with deliberate recklessness: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (iii) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Plaintiffs and other members of the Class in connection with their purchases of CytoDyn common stock in an effort to maintain artificially high market prices during the Class Period for CytoDyn common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5. As alleged herein, the material misrepresentations contained in, or the material facts omitted from, Defendants' public statements included, but were not limited to, materially false or misleading statements and omissions during the Class Period, as alleged in Section V.

537. In addition to the duties of full disclosure imposed on Defendants as a result of making affirmative statements and reports to the investing public, Defendants also had a duty to disclose information required to update and/or correct their prior statements, misstatements, and/or omissions, and to update any statements or omissions that had become false or misleading as a result of intervening events. Further, Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including accurate and truthful information with respect to the Company's operations, so that the market price of the Company's common stock would be based on truthful, complete, and accurate information.

538. Defendants' material misrepresentations and/or omissions were made knowingly, with deliberate recklessness, and without a reasonable basis, for the purpose and effect of

concealing from the investing public the relevant truth, and misstating the intrinsic value of CytoDyn common stock. By concealing material facts from investors, Defendants maintained artificially inflated prices for CytoDyn common stock throughout the Class Period.

539. As a result of the dissemination of the materially false or misleading information and/or failure to disclose material facts, as set forth above, the market price of CytoDyn common stock was artificially inflated throughout the Class Period. In ignorance of the fact that market prices of CytoDyn common stock were artificially inflated, and relying directly or indirectly on the false or misleading statements made the Defendants or upon the integrity of the market in which the securities traded, and/or in the absence of material adverse information that was known to or recklessly disregarded by CytoDyn and the Individual Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired CytoDyn common stock during the Class Period at artificially inflated prices and were damaged thereby.

540. At the time of the material misrepresentations and/or omissions, Plaintiffs and the other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class known the truth underlying Defendants' materially false or misleading statements alleged herein and the intrinsic value of CytoDyn common stock, Plaintiffs and the other members of the Class would not have purchased or otherwise acquired CytoDyn common stock at the artificially inflated prices that they paid.

541. Defendants' material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing from the investing public the relevant truth, and misstating the intrinsic value of CytoDyn stock. By concealing material facts from investors, Defendants maintained the Company's artificially inflated securities prices throughout the Class Period.

542. By virtue of the foregoing, CytoDyn and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other Class members

suffered damages in connection with their purchases and/or acquisitions of CytoDyn common stock during the Class Period

COUNT II

FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

543. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein. This Count is asserted against the Individual Defendants pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), on behalf of Plaintiffs and all other members of the Class.

544. During the Class Period, each of the Individual Defendants was a controlling person of CytoDyn within the meaning of Section 20(a) of the Exchange Act. By reason of their high-level positions at CytoDyn and their participation in and/or awareness of the Company's operations and/or intimate knowledge of the materially false or misleading statements and omissions of material fact in statements filed by the Company with the SEC and/or disseminated to the investing public, each of the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company and its executives, including the content and dissemination of the various statements that Plaintiffs contend were materially false or misleading.

545. Each of the Individual Defendants exercised day-to-day control over the Company and had the power and authority to cause CytoDyn to engage in the wrongful conduct complained of herein. In this regard, each of the Individual Defendants was provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiffs to be materially misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

546. Each of the Individual Defendants was a direct participant in making, and/or made aware of the circumstances surrounding, the materially false or misleading representations and omissions during the Class Period, as alleged in Section V. Accordingly, each Individual Defendant was a culpable participant in the underlying violations of Section 10(b) alleged herein.

547. As set forth above, CytoDyn violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of CytoDyn and, as a result of their own aforementioned conduct, each of the Individual Defendants is liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as CytoDyn is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Plaintiffs and other members of the Class who purchased or otherwise acquired CytoDyn common stock during the Class Period at artificially inflated prices.

548. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases and/or acquisitions of CytoDyn common stock during the Class Period.

COUNT III

FOR VIOLATIONS OF SECTION 20A OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

549. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

550. This Count is asserted for violations of Section 20A of the Exchange Act, 15 U.S.C. § 78t-1(a) on behalf of Plaintiffs and all other members of the Class who purchased shares of CytoDyn common stock contemporaneously with the sales of CytoDyn common stock by Defendants Pourhassan, Kelly, and Mulholland while they were in possession of MNPI as alleged herein.

551. Section 20A(a) of the Exchange Act provides that "[a]ny person who violates any provision of [the Exchange Act] or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information shall be liable . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased . . . securities of the same class."

552. As set forth herein, Defendants Pourhassan, Kelly, and Mulholland violated Section 10(b) of the Exchange Act, Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act for the reasons stated in Counts I and II above. Additionally, Pourhassan, Kelly, and Mulholland further violated Exchange Act Section 10(b), Rule 10b-5, and Rule 10b5-1 (17 C.F.R. § 240.10b5-1) by selling shares of CytoDyn common stock while in possession of MNPI concerning leronlimab, as alleged herein, which information they had a duty to disclose, and which they failed to disclose in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as more fully alleged herein. *See* Section VIII.

553. Contemporaneously with Pourhassan's, Kelly's, and Mulholland's insider sales of CytoDyn during the Class Period, Plaintiffs purchased shares of CytoDyn common stock while Pourhassan, Kelly, and Mulholland were in possession of adverse MNPI as alleged herein.

554. Upon information and belief, other Class members purchased shares of CytoDyn common stock contemporaneously with Defendant Pourhassan's, Kelly's, and Mulholland's insider sales of CytoDyn common stock.

555. Plaintiffs and other members of the Class have been damaged as a result of the violations of the Exchange Act alleged herein.

556. By reason of the violations of the Exchange Act alleged herein, Defendants Pourhassan, Kelly, and Mulholland are liable to Plaintiffs and other members of the Class who purchased shares of CytoDyn common stock contemporaneously with Pourhassan's, Kelly's, and Mulholland's respective sales of CytoDyn common stock during the Class Period.

557. Plaintiffs and the other members of the Class who purchased contemporaneously with Pourhassan, Kelly, and/or Mulholland's respective insider sales of CytoDyn securities seek disgorgement by Pourhassan, Kelly, and Mulholland, as applicable, of profits gained or losses avoided from Pourhassan's, Kelly's, and Mulholland's respective transactions in CytoDyn common stock contemporaneous with Plaintiffs and other members of the Class.

558. This action was brought within five years after the date of the last transaction that is the subject of Pourhassan's, Kelly's, and/or Mulholland's violation(s) of Section 20A, and, with respect to the underlying violations of Section 10(b) of the Exchange Act alleged in this Count and in Count I above, was brought within five years after the date of the last transaction that violated section 20A of the Exchange Act by Pourhassan, Kelly, or Mulholland.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for judgment as follows:

A. Determining that this action is a proper class action maintained under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure;

B. Declaring and determining that Defendants violated the Exchange Act by reason of the acts and omissions alleged herein;

C. Awarding Plaintiffs and the Class compensatory damages against all Defendants, jointly and severally, in an amount to be proven at trial together with prejudgment interest thereon;

D. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

E. Granting such other and further relief as the Court deems just and proper.

XIV. JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Dated: December 21, 2021

Respectfully submitted,

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