The Honorable Benjamin H. Settle

REDACTED PUBLIC VERSION

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

SECOND 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 March 30, 2022 (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); (ix) documents produced in this litigation by Defendants; and (x) 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 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 Defendants': (i) materially false and misleading statements concerning (a) CytoDyn's submission to the United States Food and Drug Administration ("FDA" or the "Agency") of a Biologics License Application ("BLA") for the use of its only drug, leronlimab, to treat HIV and its subsequent receipt of a Refuse to File ("RTF") letter from the FDA, and (b) the use of leronlimab to treat patients diagnosed with COVID-19; and (ii) fraudulent scheme or course of conduct to promote leronlimab to treat COVID-19. As reflected in exhaustive detail herein based on more than 100,000 documents produced by Defendants in this action, Defendants violated Section 10(b) and Rule 10b-5(a), (b), and (c), as well as Section 20(a) and Section 20A, of the Securities Exchange Act of 1934.

2. Since October 2012, CytoDyn has focused on the development and commercialization of a single drug, leronlimab, seeking to identify applications for its use. By the start of the Class Period on March 27, 2020, CytoDyn had identified two parallel avenues by which leronlimab could achieve regulatory approval, and thus provide revenues for the Company: HIV and COVID-19. However, as of the date of this Complaint, CytoDyn has yet to announce that the FDA has authorized it to market or sell leronlimab in the United States. As a result, the Company earns virtually no revenues and remains effectively insolvent while facing significant debts.

3. This is likely because virtually everything Defendants said to investors regarding these indications throughout the Class Period was a lie aimed at giving investors a materially misleading impression of the likelihood of FDA approval for one or both indications. In a pattern of fraudulent conduct, Defendants trumpeted dozens of submissions to and nonpublic communications with the FDA regardless of their significance in order to promote CytoDyn and its stock to investors, making materially false and misleading statements about the content and relative strength of CytoDyn's HIV and COVID-19 prospects, and then amplified these

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

unsubstantiated claims through the Company's paid-for promotional outlets. When the nonpublic communications with the FDA [redacted] Defendants lied about that too, publicly mischaracterizing [redacted]

4. The market accepted Defendants' lies as truth and investors drove the price of a "penny stock" as high as $10 a share, while Defendants exploited their fraudulent conduct to, among other things, dump 7.8 million of their own shares at inflated prices, for more than $30 million in proceeds. CytoDyn's stock price remained elevated until a series of disclosures revealed the relevant truth about the Company's deeply flawed leronlimab program.

5. **HIV.** By early 2020, Defendants had touted a supposedly forthcoming BLA application for leronlimab as a combination HIV therapy for years, but had yet to actually submit to the FDA a complete BLA. [redacted]

6. For example, after the FDA determined that the 350 mg dose tested in CytoDyn's pivotal Phase 2b/3 trial for a combination HIV therapy, known as CD02, was suboptimal for the intended treatment population and the safety data generated by the CD02 trial was unreliable, the Agency specifically identified the additional data CytoDyn needed to include in a complete BLA submission—namely, safety and efficacy data from another trial, known as CD03, to support the "to be marketed" dose of 700 mg. According to the FDA, the failure to include this data in the BLA would lead to a Refuse to File action—a complete rejection of the BLA before any substantive review by the FDA. In other words, without the CD03 safety and efficacy data, the odds that the FDA would accept the BLA for filing and review were exceedingly low.

7. [redacted]

[redacted] Without a successful BLA, CytoDyn could not market and sell leronlimab in the U.S. and get out from under the yoke of its substantial and increasing operating losses.

8. To speed the process, Defendants tried to take a number of short cuts, [redacted]

9. Meanwhile, the delay in submitting the complete BLA was weighing on CytoDyn's stock price. By early 2020, Defendant Pourhassan had had enough. [redacted] This pressure campaign culminated in an April 14, 2020 email wherein Pourhassan directed Amarex to file the BLA by April 24, 2020, despite its clear gaps, "***even if we are short in no matter what portion of whatever it is that we are short***."

10. While Defendants publicly announced that CytoDyn had filed a "complete" BLA on April 27, 2020, [redacted] On May 4, 2021, just days after Pourhassan and Kelly cashed in through millions of dollars of CytoDyn stock sales, Defendants issued a public mea culpa – the BLA was not complete but would be by May 11, 2020. On the news, the stock price declined precipitously.

11. After CytoDyn made a further submission to the FDA on May 11, 2020, Defendants again touted the purportedly complete BLA submission, hyping the forthcoming FDA response and timeframe for its substantive review and potential approval of the BLA. But on July 8, 2020,

Defendants received an RTF letter from the FDA. The 21-page nonpublic letter identified more than 100 deficiencies in the BLA, including the failure to provide efficacy and safety data from the CD03 trial that the FDA had repeatedly called for and CytoDyn agreed to submit with the BLA.

12. Defendants publicly announced CytoDyn's receipt of the RTF on July 13, 2020 before trading, prompting another sharp decline in the Company's stock price on heavy volume. In a subsequent conference call, Defendants tried to spin the substance of the RTF, telling investors that the FDA was not requiring any additional trials but merely seeking further information, data, and analyses from the ongoing CD03 trial—and, critically, that CytoDyn possessed the data necessary to resubmit the BLA by the end of 2020. Unbeknownst to investors, these assertions were belied by [redacted] and the text of the RTF itself.

13. On September 16, 2020 following further nonpublic communications with the FDA, Defendants were forced to announce that they could no longer commit to a timeline to resubmit the BLA following the RTF. In response, the price of CytoDyn's stock again tumbled.

14. [redacted] Defendants continued to try to spin the scope of the work they needed to accomplish to address the RTF letter and mislead investors as to CytoDyn's ability to finish the job. In fact, [redacted] much of which became inaccessible following a dispute with Amarex.

15. **COVID-19.** At the same time, the exploding COVID-19 pandemic presented a second, golden opportunity for Defendants to promote CytoDyn to investors and, potentially, achieve emergency authorization to market and sell leronlimab and (finally) generate revenues. There were just two problems—[redacted]

16. [redacted]

17. In public statements to investors, Defendants trumpeted the FDA's [redacted] reception of the proposed COVID-19 clinical trials as confirmation that the FDA believed in leronlimab as a COVID-19 therapeutic and would soon authorize the Company to market and sell leronlimab on an emergency basis (known as Emergency Use Authorization or "EUA") to treat COVID-19. Before the two FDA-authorized COVID-19 clinical trials—CD10 for mild-to-moderate patients and CD12 for severe and critically-ill patients—completed enrollment, Defendants breathlessly touted to investors one-off emergency approvals for the use of leronlimab in severely ill patients (known as eINDs) despite the fact that [redacted]

18. In August 2020, Defendants announced the results of the first COVID-19 clinical trial, CD10. In reality, the trial had ***missed its primary and all of its secondary endpoints,*** so [redacted] telling [redacted] and investors that CD10 had, in fact, met a purportedly important secondary endpoint ("NEWS2") and that the overall trial results supported the efficacy and safety of leronlimab to treat COVID-19. Based on the CD10 results, Defendants also told investors that CytoDyn had "request[ed]" EUA from the FDA.

19. [redacted]

[redacted]

20. After hyping the CD10 trial results and the EUA request for over a month, on September 16, 2020, Defendants disclosed to investors that CytoDyn had not requested an EUA for mild-to-moderate COVID-19 results (but an Agency opinion on the question) and the FDA would not grant the Company an EUA. On the news (and the simultaneous disclosure of the BLA delays, noted above), CytoDyn's stock price declined.

21. Thereafter, beginning on March 5, 2021, Defendants publicly disclosed the results of the CD12 trial over four days in six press releases, a conference call, and a Form 8-K. Like CD10, CD12 ***failed to meet its primary and secondary endpoints***. In order to spin these results, Defendants presented "statistically significant" p-values obtained through post-hoc analyses for certain trial population subgroups for the primary and secondary endpoints to supposedly show that leronlimab was safe and efficacious in critically ill COVID-19 patients. Based on these analyses, Defendants claimed that the Company had multiple regulatory pathways to approval in the U.S. and abroad. Despite Defendants' efforts to repackage negative results as positive through statistically invalid analysis, the price of CytoDyn's stock declined on March 8-9, 2020.

22. Defendants repeated their claims regarding the CD12 results and various regulatory pathways to approval in myriad press releases, interviews, and nearly weekly calls with investors in March and April 2021 in order to [redacted]

23. The FDA [redacted] before finally going public on May 17, 2021 with an unprecedented "Statement on Leronlimab." Seemingly fed up with Defendants' repeated mischaracterizations [redacted]

[redacted] the FDA broke with its practice of not commenting on unapproved drugs and publicly refuted many of Defendants' false and misleading statements about the CD10 and CD12 trial results. In response to the FDA's statement, the Company stock price once again plunged.

24. Undeterred, however, Defendants continued to misrepresent both the FDA's position and the data concerning the safety and efficacy of leronlimab to treat COVID-19 well into the fall of 2021.

* * *

25. The music stopped altogether for Defendants in 2022. In January 2022, CytoDyn's board of directors terminated Pourhassan as CEO and demoted Kelly from his role as Chairman of the Board. On February 22, 2022, investors learned that the FDA had hit the Company with a Warning Letter for continuing to misrepresent the results of the CD12 trial following the FDA's May 17, 2021 Statement on Leronlimab. In response, CytoDyn and the promotional outlet, Proactive Investors, scrubbed their respective websites of all content that the FDA found had created a "misleading impression" with respect to the leronlimab's use to treat COVID-19.

26. Finally, on March 30, 2022, Defendants announced that the FDA had slapped CytoDyn with a devastating partial clinical hold on its HIV program, and a full clinical hold on its COVID-19 program, which meant that CytoDyn's programs for developing leronlimab in HIV and COVID-19 were indefinitely frozen. With this final revelation of the relevant truth, CytoDyn's stock price declined once again.

27. Defendants' brazen fraudulent conduct inflicted massive losses on investors. This action seeks a remedy for those injuries.

II. JURISDICTION AND VENUE

28. 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.

29. 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.

30. 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.

31. 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

32. 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.

33. 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.

34. 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.

35. 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

36. 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."

37. Defendant Pourhassan served as CytoDyn's CEO, President, and as a BoD member from 2012 until he was terminated on January 24, 2022. He was appointed to the CytoDyn BoD 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.

38. 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. Mulholland stepped down as CFO

on or around May 18, 2021 but continued in the role of Senior Vice President of Finance and advisor to CytoDyn.

39. Defendant Scott A. Kelly ("Kelly") has been a member of the BoD of CytoDyn since April 2017. In December 2018, he was named Chairman of the CytoDyn's BoD. In July 2019, 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. On January 24, 2022, Kelly stepped down as Chairman of CytoDyn's BoD.

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

41. During the Class Period, the Individual Defendants, as senior officers and/or directors of CytoDyn, were privy to confidential, proprietary, and material adverse nonpublic 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 BoD 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.

42. 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.

43. 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.

44. 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.

45. 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. Non-Party Speakers

46. Dr. Kush Dhody ("Dhody") was Senior Vice President of Clinical Operations at Amarex Clinical Research, CytoDyn's clinical research organization during the Class Period.[2] [redacted] While Amarex served as CytoDyn's CRO, Dr.

[2] In particular, Amarex is a 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.

Dhody made statements as a representative of CytoDyn when participating in interviews and investor conference calls.

47. Kazem Kazempour, Ph.D. ("Kazempour"), served as Amarex's President and CEO during the Class Period. [redacted]

48. Bruce Patterson, M.D. ("Dr. Patterson"), is the CEO of IncellDX, a diagnostic company that began providing technical support to CytoDyn [redacted] Dr. Patterson served as a consultant and representative of CytoDyn from October 2018 to May 2020. While he served as a consultant for CytoDyn, Dr. Patterson made statements as a representative of CytoDyn when participating in interviews and investor conference calls.

49. Jacob Lalezari, M.D. ("Dr. Lalezari"), was the CEO and Medical Director of Quest Clinical Research during the Class Period and served as Principal Investigator for clinical trials involving leronlimab. He was appointed CytoDyn's Interim Chief Medical Officer on or around March 12, 2020. During the Class Period, Dr. Lalezari made statements as a representative of CytoDyn when participating in interviews and investor conference calls.

50. Mahboob Rahman ("Dr. Rahman"), Ph.D., served as CytoDyn's Chief Scientific Officer beginning in October 2020. Dr. Rahman's last day of employment in this position was April 5, 2021. During the Class Period, Dr. Rahman made statements as a representative of CytoDyn when participating in interviews and investor conference calls.

51. Nitya Ray ("Dr. Ray") served as CytoDyn's Chief Technology Officer throughout the Class Period. During the Class Period, Dr. Ray made statements as a representative of CytoDyn when participating in interviews and investor conference calls.

52. Chris Recknor, M.D. ("Dr. Recknor"), joined CytoDyn in August 2020 as Vice President of Clinical Development. He began serving as CytoDyn's Chief Operating Officer in March 2021 and currently serves as CytoDyn's Senior Director of Research and Development.

During the Class Period, Dr. Ray made statements as a representative of CytoDyn when participating in interviews and investor conference calls.

IV. SUBSTANTIVE ALLEGATIONS OF DEFENDANTS' FRAUD

A. CytoDyn's Lone Potentially Marketable Product: Leronlimab

53. 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 various 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 yet to recognize any material revenues and, therefore, has yet to recognize any profits.

54. According to CytoDyn's SEC filings, leronlimab is "a monoclonal antibody C—C chemokine receptor type 5 ('CCR5') receptor antagonist" that "target[s] . . . the immunologic receptor CCR5." "The CCR5 receptor is a protein located on the surface of various cells including white blood cells" where "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 and movement in the body. "The CCR5 receptor has been identified as a target" for therapies in a number of diseases and afflictions, including "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."

55. Leronlimab is a type of drug known as a "biological" or biologic product, which the FDA defines 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).[3] Biologics like leronlimab are derived from living material as opposed to synthesized in a lab. As discussed in the following section, in the United States, CytoDyn is not able to market or sell leronlimab as a medical treatment unless and until it submits a Biologic License Application (or BLA) to the FDA, and receives FDA approval for a specific indication and treatment population.

56. Leading up to and during the Class Period, CytoDyn's financial success, e.g., recognizing revenues (let alone profits) from the sale of leronlimab, hinged on the Company's ability to obtain regulatory approval to market and sell leronlimab in the United States. Absent sufficient 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.

B. CytoDyn Incurs Massive Annual Operating Losses

57. CytoDyn has not generated material amounts of 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. CytoDyn's accumulated deficit also jumped from $229.4 million in 2019 to $354.7 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
2021	$154,674,000

[3] *Public Health Service (PHS) Act*, Section 351.

58. Since it became a public company, CytoDyn's auditor issued a "going concern" warning following every quarterly or annual reporting period regarding CytoDyn's ability to continue as a business: "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" and "[t]here is no assurance that we will be able to adequately fund our operations in the future."

C. CytoDyn Needs to Convince Investors it Can Gain Regulatory Approval to Market and Sell Leronlimab

1. CytoDyn Focuses its Efforts on HIV

59. 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. Prior to the start of the Class Period, Defendants were largely focused on one indication: utilizing leronlimab in a combination therapy to treat heavily treatment experienced ("HTE") HIV patients.

60. CytoDyn's predecessor company, Progenics, received a "Fast Track" designation from the FDA for leronlimab in HIV [redacted] CytoDyn completed its first Phase 2 study of leronlimab as a treatment for HIV patients (CD01) in January 2015. The Company started its Phase 2b/3 "pivotal" trial ("CD02") to study leronlimab in a combination therapy for HTE HIV patients ("CD02 population") in October 2015. CytoDyn launched a third study, a Phase 3 "strategic" trial ("CD03") to assess leronlimab as a monotherapy for HIV ("CD03 population") in 2016.

61. [redacted]

[redacted]

62. [redacted]

[redacted]

63. [redacted]

[redacted]

64. [redacted]

[redacted]

[redacted]

65. [redacted]

[redacted]

2. [redacted]

66. On July 16, 2018, CytoDyn announced that CD02 had met its primary endpoint. Following extensive meetings and correspondence with the FDA, Defendants began to put together in earnest a BLA for approval of leronlimab to treat the CD02 population. However, [redacted]

67. [redacted]

[redacted]

68. [redacted]

[redacted]

69. [redacted]

[redacted]

70. [redacted]

[redacted]

[redacted]

71. [redacted]

[redacted]

72. [redacted]

[redacted]

73. [redacted]

[redacted]

[redacted][4]

74. [redacted]

75. [redacted]

76. [redacted]

[4] Receptor occupancy ("RO") assays are designed to quantify and characterize the binding profile of therapeutic drugs to their targets on the cell surface, and are frequently used to generate pharmacodynamic (PD) biomarker data in nonclinical and clinical studies of biopharmaceuticals. When combined with the pharmacokinetic (PK) profile, RO data can establish PKPD relationships, which are crucial for informing dose decisions. And RO is determined by measuring the ability of a dose of the test drug to compete with binding of a radiotracer to the receptor.

[redacted]

77. [redacted]

[redacted]

78. [redacted]

[redacted]

79. [redacted]

[redacted]

80. [redacted]

[redacted]

[redacted]

81. [redacted]

[redacted]

82. [redacted]

[redacted]

83. [redacted]

84. CytoDyn did not share these BLA-related communications, nor other specific guidance it had received from the FDA prior to the start of the Class Period, prior to the April and May 2020 HIV BLA submissions to the FDA, or when the Company received the RTF letter in July 2020. However, as is discussed more fully below, multiple shortcomings in the HIV BLA submission that CytoDyn eventually made, including many involving insufficient data and analyses that the FDA had specifically advised CytoDyn and CytoDyn expressly agreed to include in full therein, caused the FDA to reject CytoDyn's BLA submission out of hand in July 2020. Specific information about the particular deficiencies in the BLA did not become public until October 26, 2021, when, in the context of litigation between Amarex and CytoDyn, the entire RTF letter was disclosed. *CytoDyn, Inc. v. Amarex Clinical Research, LLC, et al.*, No. 21-cv-02533 (D. Md. Oct. 4, 2021).

85. Investors, however, remained unaware until the March 30, 2022 disclosure of the FDA's partial clinical hold on CytoDyn's HIV IND of [redacted]

3. From Late-2019 into Early 2020, CytoDyn Fails to Meet its Stated HIV BLA Filing Goal, While Separately, Defendants Seize Upon Leronlimab's Potential Use as a COVID-19 Therapeutic

86. Throughout 2019, CytoDyn asserted publicly that it would file the HIV BLA by year end 2019. On January 13, 2020, after failing to file the BLA, CytoDyn announced that it would complete its submission in the first calendar quarter of 2020.

87. Meanwhile, in January 2020, the SARS-CoV-2 virus and the coronavirus disease 2019 it caused a/k/a COVID-19 was spreading rapidly in numerous countries, including the United States. On January 31, 2020, the U.S. Secretary of Health and Human Services declared that, with respect to COVID 19, "a public health emergency exists and has existed since January 27, 2020, nationwide." While efforts to study COVID 19 were underway, the virus was poorly understood, and effective treatments were not yet identified. Stories of the virus's worsening outbreak, and desperate medical and public health efforts to contain and treat it, gripped the globe.

88. Defendants did not let the opportunity pass. [redacted]

89. Defendants issued their first COVID-19 press release on January 28, 2020, declaring that it was "exploring leronlimab as a potential treatment for [COVID-19] patients." The market reaction to the press release was unmistakable: immediately following its issuance, the daily trading volume in CytoDyn's common stock jumped by 60%. Defendants had struck upon a rich vein.

90. Thereafter, [redacted] CytoDyn submitted an Investigational New Drug ("IND") application, seeking the Agency's approval to conduct clinical research to determine whether leronlimab was effective in treating

patients with COVID-19. Simultaneously, the Company submitted a draft protocol for a Phase 2 study of leronlimab for mild-to-moderate COVID-19 patients ("CD10").

91. [redacted]

92. In an apparent effort to enflame investors about CytoDyn's [redacted] hypothesis, with respect to COVID-19, [redacted]

93. [redacted]

94. Defendants appointed Dr. Lalezari CytoDyn's interim Chief Medical officer on March 12, 2020. [redacted]

[redacted]

95. Nevertheless, on March 19, 2020, CytoDyn issued a press release touting the FDA's one-off approval of a pair of emergency IND ("eIND") requests submitted by a New York City-based doctor for the treatment of two patients with severe COVID-19.

96. Thereafter, [redacted]

97. [redacted]

98. [redacted]

[redacted]

99. [redacted]

[redacted]

100. With respect to eIND requests, [redacted]

[redacted]

D. Throughout the Class Period, CytoDyn Touts Two Indications for Leronlimab With Purported Substantial Promise for FDA Approval: HIV and COVID-19

1. CytoDyn Generates Strong Positive Reaction to its Public Statements Touting Leronlimab vis-à-vis COVID and HIV

101. By the end of March 2020, CytoDyn was actively touting two supposedly promising pathways to FDA approval for leronlimab to investors, HIV and COVID-19. In their public statements throughout the Class Period, Defendants toggled between these two leronlimab "irons in the fire" opportunistically and misleadingly, in an effort to spin investors and attract capital based on overblown, unfounded claims about leronlimab, its safety, its apparent effectiveness as a treatment for COVID and/or HIV, and its prospects for regulatory approval.

102. On the first day of the Class Period, March 27, 2020, CytoDyn issued two press releases touting supposed positive developments with respect to leronlimab and its potential use as a treatment for COVID. In the first release, Defendants stated, "the FDA suggested the Company

file a second randomized protocol for all COVID-19 patients in severe condition ***so as to preclude each physician from filing an emergency IND for every patient to be treated with leronlimab***." The second release stated that "***evaluation of test results*** from the first four patients" with severe COVID who were treated under eINDs (hereafter eIND results or data) "***suggests immunological benefit within three days following treatment with leronlimab*** . . . ."

103. Also on March 27, 2020, Pourhassan participated in an interview conducted by Proactive Investors in which, with respect to the eIND data, Pourhassan stated that "***the cytokine storm [data] is really strong. Obviously FDA has talked to us about filing a protocol for that***."[5] Pourhassan added: "And then when perhaps the results of these patients were coming out ***the FDA has told us that as of yesterday that we would also like you to do another protocol that would treat severe patient***."

104. On March 30, 2020, investment analyst firm H.C. Wainwright & Co. ("H.C. Wainwright") reiterated Defendants' recent claims about leronlimab and COVID-19, in a report entitled, "*Promising Preliminary Results in COVID-19 Patients; Reiterate Buy*." The report stated, "these preliminary [eIND] data demonstrate the potential of leronlimab to help hospitalized COVID-19 patients recover from pulmonary inflammation that drives mortality and the need for ventilators . . ." and noted that "the FDA suggested that [CytoDyn] file a second randomized, double-blind, placebo controlled study for all COVID-19 patients in severe condition . . . ."

105. Also on March 30, 2020, CytoDyn submitted to the FDA a draft Phase 2b/3 protocol to study the use of leronlimab to treat severe and critically ill COVID-19 patients ("CD12"). Thereafter, Pourhassan participated in an interview conducted by Proactive Investors on March 31, 2020, in which he hyped the FDA's supposed eagerness around leronlimab as a COVID-19 therapeutic, given its putatively "positive results," stating, "[a]nd the ***FDA had asked***

[5] Cytokine storm is an umbrella term encompassing several disorders of immune dysregulation characterized by constitutional symptoms, systemic inflammation, and multiorgan dysfunction that can lead to multiorgan failure if inadequately treated.

us beside this protocol [i.e., CD10]***, which is for COVID patients with mild or moderate condition, they said also send in a protocol, which is a Phase 3 for severe patient population*** [i.e., CD12]. So we also are working on that . . . . ***[W]hat we seen in the early results*** is . . . some of the [severe] patients were able to get off the . . . ventilator and also one of the patients . . . is going to be released from the hospital. Now ***that's major results***. . . . . ***So we're very, very happy that the FDA has worked with us so quickly and able to expedite this since there was some positive results***."

106. On April 1, 2020, Pourhassan stated in an interview with Yahoo! Finance, that "***[t]he results . . . from the first four patients"*** demonstrated an ***"immunological benefit"*** from the use of leronlimab. Pourhassan further stated, "***that was a very big start for us with the FDA*** when we said that our scientists believe we can stop cytokine storm . . . ."

107. On April 2, 2020, Defendants issued another press release touting leronlimab's supposed effect on COVID-19 patients, noting that CytoDyn had filed the CD12 protocol with the FDA related to severe and critically-ill COVID-19 patients.

108. Analysts at H.C. Wainwright embraced Defendants' representations, and, in a report dated April 3, 2020, increased their valuation of CytoDyn by nearly ***$800 million***, and ***doubled*** their price target for CytoDyn stock to $3.00 per share The report, entitled, "*More Positive COVID-19 Clinical Results; Phase 2 Trials Initiated; Raising PT to $3,*" stated "Yesterday, CytoDyn announced that the three-day effect of leronlimab in eight severely ill COVID-19 patients (out of 10 patients enrolled under the emergency Investigational New Drug (IND) protocol) showed a significant improvement in immunologic biomarkers." H.C. Wainwright concluded, "we have added potential sales of leronlimab as COVID-19 therapy to our valuation," leading to an increase in "estimated market value" from $902M to $1.7B and an increase in its "12-month price target to $3 from $1.50 per share."

109. Despite Defendants' public hype of leronlimab to treat COVID-19 during the first week of the Class Period, the nonpublic reality was quite different. [redacted]

[redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

[redacted]

110. [redacted]

[redacted]

111. [redacted]

Pourhassan continued to publicly tout leronlimab as a COVID-19 therapeutic. On April 7, 2020, he gave an interview on FOX Business News, in which he stated:

> [T]he good thing about leronlimab is it had 840 patients use that in HIV with zero serious adverse events. . . . Now, when we went forward with the coronavirus, we were very surprised, pleasantly that the first two patients, one of them . . . self-extubated immediately within three days. ***The results that's coming out right now in the first 10 patients . . . we have seen very spectacular results and we are sending that to the FDA for the first seven patients that have gone seven days***. . . . Now we have seven day data that is really strong. ***So we're sending to FDA and asking for emergency approval***, perhaps.

112. On April 9, 2020, CytoDyn issued a press release and Pourhassan participated in an interview conducted by Proactive Investors, stating similar assertions. The press release

asserted that blood samples from severely ill COVD patients "***Clearly Indicate Leronlimab Has Significantly Reduced the Cytokine Storm in All (7) Patients and All Patients Demonstrated Immunological Benefit*** at Both Day 3 and Day 7." In the interview, Pourhassan stated, "[***T]hese results are - there is no joke here. Now, this is something that has been very, very carefully analyzed. These patients show immunological benefit. They show a cytokine storm reduction.***"

113. That same day, [redacted]

114. [redacted]

115. [redacted]

2. [redacted] CytoDyn Submits the HIV BLA Without the FDA-Required Data and Information

116. By April 2020, Pourhassan was unable to wait for the HIV BLA submission any longer. Defendants' many COVID-related statements had initially generated investor interest and stock price and volume increases, but CytoDyn's stock price was still not consistently at the level Pourhassan wanted to deliver—a fact that Pourhassan utilized to repeatedly pressure Amarex to submit the HIV BLA despite its clear shortfalls in required data and analyses.

117. [redacted]

118. This pressure culminated in an April 14, 2020, e-mail to Drs. Kazempour and Dhody, as well as Dr. Ray, CytoDyn's Chief Technology Officer, wherein Pourhassan demanded that the HIV BLA be submitted to the FDA ***regardless*** of the internally well-known gaps and data deficiencies it contained. He wrote: "Today we have so far in 1 hour almost 20% drop in our stock price. . . . 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.***"

119. Pourhassan's April 14, 2020 e-mail did not become public until October 26, 2021, when Amarex filed it as an exhibit to Dr. Kazempour's sworn declaration in its litigation against CytoDyn. Importantly, Dr. Kazempour also stated under oath in his declaration attached to the

October 26, 2021 filing that Pourhassan had been "warned" about the deficiencies in the HIV BLA: "***Pourhassan directed Amarex to file the BLA prematurely, knowing it was incomplete, lacking in appropriate content and not ready for submission***." Notably, [redacted]

120. CytoDyn submitted the HIV BLA to the FDA on April 27, 2020. Defendants did so despite a litany of deficiencies in the FDA-required information, data, and analyses in the submission package, and about which Defendants knew or were deliberately reckless in not knowing (but, in any event, did not disclose to investors). Indeed, [redacted]

121. Nevertheless, 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 . . . .

122. Defendants reiterated in multiple subsequent press releases and public statements that the BLA filing was completed.

123. Likewise, during an April 27, 2020 conference call with investors, Pourhassan represented that the HIV BLA filing was complete: "***The good news is, CytoDyn just filed the full BLA last night***."

124. Conveying an impression of multiple auspicious avenues for leronlimab, Drs. Lalezari and Patterson went on to tout the drug's supposed performance in treating COVID-19 patients during the same call. On CytoDyn's behalf, Dr. Patterson stated that "leronlimab decreases

plasma viral loads," and that it was "remarkable for one drug to restore the immune system and decrease the viral burden in these patients." Additionally, Dr. Lalezari claimed on behalf of CytoDyn that "[i]t's clear this drug is working. It's working better than we could have ever imagined."

125. Defendants repeatedly made such claims about "data" showing leronlimab "working" solely on the basis of a results and data from a handful of eIND patients—[redacted]

126. Analyst H.C. Wainwright accepted Defendants' positive disclosures about both HIV and COVID-19 in an April 28, 2020 report, and increased the Company's valuation again, this time by ***$700 million***, and its target price per share to $4.00.

3. [redacted] While Pourhassan and Kelly Reap Windfalls on Illicit Stock Sales

127. [redacted]

128. Alongside the news of the HIV BLA submission, CytoDyn's stock price climbed above $3.00 per share in late April 2020. Defendants Pourhassan and Kelly seized their chance, and enriched themselves through massive illicit insider stock sales.

129. Between April 30 and May 4, 2020, Pourhassan exercised options and sold over 4.8 million shares, for approximately ***$15 million*** in total proceeds. On May 1, 2020, Defendant Kelly exercised options and sold 1.2 million shares, enjoying ***$3.9 million*** in total proceeds.

4. The Market Learns that the HIV BLA was Not Complete, Putting CytoDyn's Stock [redacted]

130. Then, buried deep within a May 4, 2020 press release, which extolled the Company's request for compassionate use clearance for leronlimab to treat COVID-19 and various eIND approvals for leronlimab, 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.

131. [redacted]

5. Defendants Ramp Up Their Strategy of Hyping Leronlimab's Purported Efficacy as a COVID-19 Therapeutic While Supposedly Backfilling CytoDyn's HIV BLA With All Needed Data

132. After their public misstep on the HIV BLA, Defendants refocused efforts on promoting leronlimab as a potential COVID-19 treatment. For instance, in a May 6, 2020 interview conducted by Proactive Investors, Pourhassan stated, "***the mechanism of action is clear***."

133. Investors accepted these representations. In an analyst report the next day, H.C. Wainwright stated, "knowledge of the mechanism of action for leronlimab in COVID-19 helps us better understand how the application of leronlimab monotherapy has led to patients' extubation and recovery" and "[t]hus, we reiterate our Buy rating and $4 price target."

134. On May 13, 2020, Defendants stated in a press release that CytoDyn had sent necessary data to the FDA regarding the HIV BLA on May 11, 2020, and "submitted a complete BLA for rolling review." That same day, H.C. Wainwright reported that "CytoDyn has confirmed that on May 11, 2020, it submitted all remaining parts of the Biologics License Application (BLA) for leronlimab" and reiterated its valuation for CytoDyn.

135. Defendants also continued to tout CytoDyn's efforts to gain the FDA's approval for a compassionate use protocol for leronlimab to treat COVID-19 and the eIND results. However, [redacted] Yet Defendants, seeking a shortcut and a headline, [redacted] —and then publicizing to investors that they had made these submissions without also disclosing the FDA's actual position with respect to these efforts. Moreover, in several instances, Defendants mischaracterized or misrepresented the FDA's position in its public statements [redacted]

136. [redacted]

[redacted]

137. [redacted]

[redacted]

138. [redacted]

[redacted]

139. [redacted]

[redacted]

[redacted]

140. On June 2, 2020, Defendant Pourhassan participated in a Wall Street Reporter Next Super Stock livestream, in which he publicly acknowledged that the FDA had told CytoDyn that it would not grant any more eIND for leronlimab because "we need you to finish the trial." Pourhassan spun the FDA's position as, "***if you believe that you have something that works, let's give it to thousands and thousands and thousands, not just 70 patients. . . . And I'm very happy to see that FDA is also looking at our manufacturing, the production capability, and all of those things, which means very, very positive for us***."

141. Then, in a June 15, 2020 interview on Proactive Investors, Pourhassan stated, "***it's very exciting to see a product like this showing the results in emergency IND*** [in] over 70 patient. No company has 70 patients emergency [IND] . . . nobody in the world. . . . ***FDA has been extremely positive with us and helping us and guiding us***."

142. [redacted]

[redacted]

143. [redacted] Defendants continued to publicly represent that the FDA was bullish on leronlimab's prospects as a COVID treatment based on eIND results. For example, on July 4, 2020, in an interview on the Dr. Been webcast, Pourhassan stated that "FDA, ***as soon as they saw what happened with [certain eIND patients], immediately FDA worked with us. They did not delay it a day. They said—you got Phase 2, go forward***."

6. The FDA Rejects Defendants' Gap-Ridden HIV BLA Submission in the Nonpublic RTF Letter

144. On July 8, 2020, Defendants' misrepresentations concerning the HIV BLA hit a wall. That day, the FDA informed CytoDyn in a nonpublic 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.

145. 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.

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

2020. Much of the missing data, the FDA reminded Defendants, was information that the FDA had specifically told Defendants must be included in the HIV BLA during numerous pre-BLA communications in 2018-2020 (as noted above) including, but not limited to, CD03 safety and efficacy data and receptor occupancy data for 350 mg, 525 mg, and 700 mg doses.

147. Critically, the RTF letter did not address whether CytoDyn needed to conduct the Phase 3 clinical trials for the CD02 and CD03 populations [redacted] Indeed, the RTF letter was silent on this issue, [redacted] and the FDA was unable to substantively review CytoDyn's BLA as reflected in the RTF Letter.

148. 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.

7. CytoDyn Misrepresents the True Substance of the RTF Letter

149. On July 13, 2020, CytoDyn stunned the market when it disclosed that the FDA had "Refuse[d] to File" the HIV BLA in press release before the market opened for trading that day. 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 the grossly inadequate application 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.

150. 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 21,148,854 shares.

151. On and after July 13, 2020, CytoDyn scrambled to perform damage control, and misleadingly assure investors that the issues the FDA had identified with the rejected BLA were not significant, and the application could be salvaged.

152. For example, Defendants' July 13, 2020 press release quoted Pourhassan stating, "We are 100% committed and confident we can provide the necessary information to the FDA as soon as possible. ***No additional trials will be required and all the information the FDA has requested is obtainable***." In a CytoDyn conference call the same day, Pourhassan stated "***We are thankful that the information needed does not require any more trials, and simply getting the information that the agency requested with the detail that they require.***" Pourhassan further stated, "[t]he information requested by the FDA is mainly for one module, the clinical, and a few minor points about manufacturing."

153. In a conference call on July 13, 2020 following the close of the market and the sharp stock price decline, Defendants attempted to reassure investors, stating that the FDA would not require CytoDyn to conduct additional clinical trials and promoting the impression that the RTF letter contained requests for additional information, analyses, and summaries tied to the recent completion of the CD03 trial, and that CytoDyn had all the data necessary to quickly resubmit the HIV BLA.

154. Market participants accepted Defendants' representations that the BLA issues that precipitated the RTF letter were limited and manageable. In reports on July 14 and 16, 2020, H.C. Wainwright stated, "Management noted that the FDA does not require any further clinical trials to be conducted but that additional analysis of completed trials needs to be performed. . . . [W]e believe the analysis could be completed in a reasonable time frame." A *Seeking Alpha* article on July 14, 2020 stated, "Dr. Dhody expressed no reservations concerning availability of data requested by the FDA."

155. The message that Defendants simply needed to perform modest re-assessments of data they already possessed, and re-package their presentation of the HIV BLA—in a process that

would take just months—was materially misleading. [redacted] Defendants, however, would not themselves come clean about the true scale of the HIV BLA shortcomings until 2022.

8. After CytoDyn's Failed HIV BLA, Defendants Heavily Promote CD10 and CD12 and Supposed Signs That Leronlimab Is an Efficacious Treatment for COVID-19

156. Defendants also increasingly touted leronlimab's potential approval as a treatment for COVID-19. In a pattern that continued throughout the Class Period, Defendants misleadingly publicized indeterminate treatment results (from the field or clinical studies) and supposedly auspicious filings and communications with the FDA about leronlimab in the COVID-19 context. These claims were unfounded and unreasonable, [redacted]

157. Beginning in late July 2020 and continuing through the second half of the year, Defendants trumpeted the supposed progress and outcomes of the CD10 Phase 2 clinical trial regarding patients with mild to moderate COVID. However, as they finalized the CD10 results and drafted the Top Line Report ("TLR"), Defendants knew or were deliberately reckless in not knowing that the CD10 results were, in fact, quite poor. [redacted]

158. On July 30, 2020, Pourhassan provided a purported update on the CD10 results during an investor conference call. He touted the supposed positive results:

> [A]s of today, we do have positive efficacy results in our CD-10 and the data is still being evaluated to find more positive aspects. In regards to our primary endpoint, clinical improvement was scored in four categories, fever, body ache, difficulty to breath and cough. We have seen improvement in day three versus day zero in leronlimab arm as compared to placebo arm.
>
> So that is the first major positive result for us . . . . a very important secondary endpoint is called NEWS2. . . . NEWS2 assesses the degree of illness that points out to any need for critical care intervention. . . . In regards to this very crucial parameter, we have seen good improvement in leronlimab arm compared to placebo arm in all evaluated days, which is day three, day seven and day 14. We are so delighted with this result. . . . We hope to have the top line report within 10 days or so.

159. That same day, with CytoDyn stock having climbed to a price of nearly $5.00 per share, Pourhassan again made insider sales. On July 30, 2020, he netted proceeds of $778,000 on these additional sales.

160. On August 5, 2020, Pourhassan and Dr. Lalezari participated in an interview with Proactive Investors, and again misleadingly played up the CD10 results and mischaracterized the FDA's supposed support. Lalezari stated, "In the CD10 what ***we saw – I think a remarkably was a very clinically significant reduction in serious adverse events***." Likewise, Pourhassan stated:

> In the CD10, we announced that we found parameters. Now, the Phase 2 is a proof-of-concept. Any parameter in your secondary outcome or primary outcome is just perfect, if you can find a perfect difference between leronlimab and placebo. We found them, and we're going to — and I told everybody — we believe it's statistically significant, and we're going to give the p-value, and we have to finalize those reports before we can give exact [numbers]. . . . Now, what does that parameter mean? That means now you go back to the FDA, you can do Phase 3, but if you're in pandemic and say — the FDA recognizes that what you found was good enough to go to approval and do, perhaps, Phase 4. That could happen — that's CD10, mild-to-moderate.

161. Defendants continued this approach on August 11, 2020. In a CytoDyn press release that day, Defendants highlighted that leronlimab "demonstrated statistically significant improvement versus placebo in key secondary efficacy endpoint, National Early Warning Score 2 scale (NEWS2)" and quoted Pourhassan as stating: "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 . . . in the U.S."

162. On August 12, 2020, CytoDyn submitted the TLR on the CD10 trial results to the FDA. At the same time, [redacted] Consistent with their typical practice, Defendants immediately publicized the submission of the TLR and misleadingly told investors that CytoDyn had "***request[ed]***" an EUA for leronlimab for mild to moderate COVID patients during a same day conference call with investors.

163. Additionally, during the August 12 investor call, Defendant Kelly emphasized the supposed extraordinary results from CD10: "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. I think that's remarkable."

164. During the same call, Dr. Lalezari stated CytoDyn's purported achievement even more strongly:

> [W]hat the study showed us is that we are able to reduce symptoms in patients that had measurable symptoms that they find . . . . But far more important and consequential as a clinician, whether it was chosen as the primary endpoint or not, are what we saw not only in NEWS2 . . . but these serious adverse events. These are the things that are clinically far more important than whether your muscle ache is a grade one or a grade two. … ***[T]he results of CD10 la[y] to rest the question of whether leronlimab works at all in COVID-19. It unquestionably does, based on clinical outcomes, and then, these much more serious outcome SAEs and NEWS2. So, the drug works . . . . I think we have our first drug that actually works in COVID-19***.

165. Carrying on the hype about the CD10 results, Defendants made statements on, e.g., August 17, 2020, re-emphasizing the supposed trial outcomes and CytoDyn's related discussions with regulators seeking near-term emergency use approvals. An August 17, 2020 CytoDyn press release entitled, "*CytoDyn Submits its Top-Line Report from its Phase 2 COVID-19 Trial to the U.S. FDA and Requests Emergency Use Approval*" quoted Pourhassan stating:

> 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.

166. Analysts at H.C. Wainwright picked up Defendants' claims. In a report dated August 17, 2020, they discussed the CD10 results that Defendants had highlighted, and stated, "[t]hese results show that leronlimab . . . in mild-to-moderate COVID-19 patients is safe and can deliver rapid improvement in symptoms associated with the coronavirus infection."

167. Defendants made numerous similar statements concerning the CD10 results in press releases, interviews, and investor calls throughout August and early September 2020.

168. At around the same time, Defendants continued to portray the refused HIV BLA as a submission that CytoDyn could readily rehabilitate. In the Company's Form 10-K filed August 14, 2020, Defendants stated that they ***"expected" to re-file the BLA by the end of 2020***. Defendants likewise characterized the RTF letter as requesting "additional information to complete [the FDA's] substantive review" of the HIV BLA and "additional analyses of completed trials." Critically, per Defendants, the RTF letter did "not require any additional clinical trials to be conducted, rather that the Company conduct specifically requested additional analysis of the completed trials data."

169. In an August 20, 2020 interview conducted by Proactive Investors, Pourhassan gave the following status update on the BLA, indicating that CytoDyn possessed all the data it needed to submit to the FDA in order to make the filing complete: "We didn't, we were not given directions to do another clinical trial. So that's always a great thing. ***All we have to do is to provide the information that we now have in the form that the FDA requests. . . . We have the data***." Pourhassan made similar representations, e.g., during a September 2, 2020 investor conference, on which, among other things, he purported to read excerpts of the RTF letter the FDA sent to CytoDyn regarding the HIV BLA.

170. [redacted]

[redacted]

171. [redacted]

[redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

[redacted]

172. Defendants did not disclose any of this negative information to investors for nearly two weeks and even then, Defendants continued to conceal material aspects of its interactions with the FDA with respect to the BLA resubmission and the CD10 results.

9. Defendants Incrementally Disclose Setbacks at the FDA With Respect HIV and COVID-19

173. On September 10, 2020, CytoDyn issued a press release announcing a Company conference call on September 16, 2020, to discuss "the very successful FDA meeting concerning CytoDyn's upcoming HIV BLA submission," and to provide "an update on the ongoing discussions with the FDA . . . for leronlimab as a treatment for COVID-19." On the September 16, 2020 conference call, which occurred after the market's close, Defendants disclosed two negative developments regarding leronlimab's prospects for regulatory approval.

174. *First*, Defendants, through comments by Dr. Dhody, explained that the FDA issued the RTF letter, in part, because it now wanted to see efficacy data from the CD03 trial that did not exist at the time of the prior submissions. As a result, "the purpose of the [September 8, 2020] meeting [wa]s to come to agreement with [the FDA] for the submission of efficacy data to support 700 mg dose." While Defendants admitted that the HIV BLA submission did not include efficacy data for the 700 mg dose, they attempted to spin that deficiency as an issue that was out of their control. In other words, it was not "the lack of expertise," but "the lack of existing underlying data from the 700 mg dose from an ongoing clinical trial [CD03]" and the FDA's need for "additional

information"—implying that the information had not been repeatedly requested by the FDA in 2018-2019—that led to the RTF.

175. Moreover, Defendants (again through Dr. Dhody) confirmed that CytoDyn had "all level of information that is needed to be submitted to" the FDA, critically, "all . . . data" necessary "to make a successful submission to" the FDA "and get [the] marketing approval for [the] HIV indication."

176. Nevertheless, when an H.C. Wainwright analyst asked Defendant Pourhassan about CytoDyn's "timeframe" to "resubmit" the application, Pourhassan refused "to give a timeframe at this time" thus confirming, at least implicitly, that issues identified in the RTF, including the lack of efficacy data for the 700 mg dose from CD03, were far more difficult to address than investors previously understood. Following these disclosures, H.C. Wainwright noted in its September 18, 2020 report that although "[m]anagement indicated that CytoDyn now has all the data required by the FDA for resubmission . . . management has decided not to disclose a time frame for the BLA resubmission at this time."

177. *Second*, addressing the much-publicized EUA application for leronlimab for mild-to-moderate COVID-19 based on the CD10 results, Pourhassan admitted that CytoDyn had ***not*** actually submitted a "formal" EUA request to the FDA for leronlimab regarding mild-to-moderate COVID-19, but instead had sought the FDA's opinion as to the success of such a request. According to Pourhassan, the "FDA is telling us right now, mild to moderate is not going to get emergency use access, that's their opinion and they recommend for us not file for that." Thereafter, in the same September 18 report, H.C. Wainwright analysts noted "[n]o leronlimab immediate-term emergency approval in COVID-19."

178. These disclosures sent CytoDyn's stock price tumbling over 15% on the next trading day. Namely, on September 17, 2020, CytoDyn's common stock price fell $0.61 per share, from a close of $4.03 on September 16, 2020, to a close of $3.42 on September 17, 2020 on heavy trading.

179. Thereafter, Defendants continued to make misleading statements to the market on both topics. On a September 23, 2020 webcast with Dr. Been, Pourhassan stated, "In regards to HIV . . . . Unfortunately, we had a refuse to file letter. But that refuse to file letter says, 'we need more data ***that you have***.' But we didn't have it when we submitted BLA, because the trial that they asked for safety was not completed. ***With that said, at least we have all the data***. . . . ." Unbeknownst to investors, [redacted]

10. Pivoting from the Stalled HIV BLA and CD10 Results, Defendants Propose a Protocol to Investigate Leronlimab's Effect on "Long Haul" COVID-19 Patients and a Resumption of the eINDs

180. On November 17, 2020, CytoDyn submitted a proposed protocol to the FDA for a clinical trial regarding the use of leronlimab on patients with "long haul" COVID-19. This trial was designated CD15. [redacted]

181. Additionally, after CytoDyn completed enrollment of its CD12 trial on December 15, 2020, [redacted]

182. [redacted]

a. [redacted]

b. [redacted]

[redacted]

183. [redacted]

[redacted]

a. [redacted]

b. [redacted]

c. [redacted]

[redacted]

184. [redacted]

[redacted]

185. [redacted]

[redacted]

186. Still, Defendants persisted in making misleading public statements regarding CytoDyn's leronlimab clinical trials and FDA reception in the COVID-19 context. For example, in CytoDyn's Form 10-Q filed January 8, 2021, and signed and certified by Pourhassan and Mulholland, the Company stated: "The topline report from the [CD10] trial, including efficacy and complete safety data demonstrated clinically significant results for the primary endpoint and statistically significant results for the secondary outcome for NEWS2[], was submitted to the FDA in August 2020."

11. [redacted]

187. [redacted]

188. [redacted]

189. [redacted]

190. And, when the FDA rejected the receptor occupancy assay or test utilized to analyze [redacted] in the RTF letter, [redacted]

[redacted] In fact, it was the receptor occupancy data issue that led Pourhassan to backtrack on the timeline to resubmit the HIV BLA during the September 16, 2020 call with investors. [redacted]

191. [redacted]

192. [redacted]

193. Up until this point, Defendants had repeatedly told investors that they had all the data necessary to resubmit the HIV BLA. In reality, however, [redacted] which was directly contrary to Defendants' repeated assurances that no further trials were required as a result of the RTF letter.

194. [redacted]

12. The Broad Failure of the Latest CD12 Trial Prompts Defendants to Again Seek Extraordinary EUA for Leronlimab, Which the FDA Again Rejects

195. [redacted] Defendants unblinded the results of the CD12 trial, and found that the trial had not met any of its primary or secondary efficacy endpoints. [redacted]

196. [redacted]

197. [redacted]

198. [redacted]

199. [redacted]

200. [redacted]

201. [redacted]

[redacted]

[redacted]

13. Defendants Further Shift to Heavy Promotions of the Leronlimab Clinical Trials and Supposed Signs That Leronlimab Is an Efficacious Treatment for COVID-19

202. Four days later, on March 5, 2021, after the close of trading, CytoDyn issued the first of several press releases publicly announcing the CD12 trial results. This first release avoided discussing the failure of the CD12 trial to reach any endpoint, and, critically the FDA's clear position as to both the failure of the CD12 trial, the subgroup analyses, and an EUA based on the CD12 results set forth in successive February 2021 nonpublic letters. Instead, the release quoted Pourhassan stating: "Our [Phase 2b/3] CD12 study demonstrates leronlimab is particularly effective in treating [critically ill COVID-19 patients]. . . . The Company . . . is concurrently working with regulators here and abroad to expedite leronlimab's approval to treat COVID-19."

203. Defendants issued a second press release on Saturday, March 6, 2021, disclosing that the primary and secondary endpoint results in the CD12 trial were "not statistically significant." CytoDyn added its positive spin, "announc[ing] . . . multiple regulatory pathways for approval of leronlimab as a treatment for critical COVID-19 patients in the U.S. . . ." and stating that it was "pleased to show strong data for critically ill COVID-19 patients," one of the subgroup populations the FDA already had branded "not . . . reliable" and "misleading" in nonpublic letters to Defendants. According to the March 6, 2021 press release, CD12 trial results boasted two "statistically significant" "p-values" for the primary endpoint, this time in the leronlimab + SoC and leronlimab + dexamethasone population subgroups, respectively.

204. Prior to the start of the trading day on Monday, March 8, 2021, Defendants reissued the key statements the March 5 and 6, 2021 press releases in one summary press release. [redacted]

[redacted]

205. After the close of trading on March 8, 2021, Defendants filed with the SEC on Form 8-K the Executive Summary previously provided to the FDA. Defendant Mulholland signed the Form 8-K. Defendants also held an investor conference call. On the call, Pourhassan did not mention what the FDA had stated to Defendants about the CD12 results in its February 2021 or March 8, 2021 letters, but asserted:

> On Friday, we announced not only very strong results of 394-patient trial but the fact that 3 regulatory agency, including U.S. FDA, are working with us and have suggested the final path to approval for COVID-19 in multiple countries, including USA. . . .
>
> I think everybody would agree that when FDA says do another trial to show that critical population is solid, your data, that means they're seeing a signal and they're seeing a need that perhaps they can work with us.

206. [redacted] the Executive Summary attached to the March 8, 2021 Form 8-K identified two "statistically significant" p-values in the leronlimab + SoC and leronlimab + dexamethasone population subgroups in the primary endpoint and one statistically significant p-value in the critically ill population subgroup for a secondary endpoint. The Executive Summary also identified a "relative reduction" in the risk of mortality in a number of subgroup populations.

207. [redacted]

208. [redacted] investors continued to accept Defendants' positive pronouncements about leronlimab's putative efficacy and promise as a COVID treatment. For example, in a March 12, 2021 article posted to *Seeking Alpha*, the author noted that "[a]fter some analysis, the company revealed a subset of patients who benefited from leronlimab." Describing these results as "encouraging," the article reflected "optimis[m] about Leronlimab's chances of moving forward in COVID-19." The article concluded by highlighting the FDA's "low bar for approval," and Remdesivir data, stating "one can see how this [CD12] data does provide an argument to pursue approval." Another *Seeking Alpha* article published on March 17, 2021, stated that the CD12 "[t]rial data is supportive of an EUA" because "leronlimab outperformed every approved or recommended drug in critically ill patients." The article further stated, "[i]t is fairly clear, given the congruency of the leronlimab CD12 trial data and the magnitude of the therapeutic benefit seen therein, that *leronlimab works*" and "that leronlimab most likely will be approved or issued a conditional Emergency Use Authorization (EUA) sometime soon." (Emphasis in original).

209. [redacted]

210. Nevertheless, five days later, CytoDyn published a press release touting the [redacted] statistical conclusions the [redacted] The press

release, entitled, "*CytoDyn's Leronlimab Decreased Mortality at 14 Days by 82% With Statistically Significant P-Value of 0.0233 Amongst Critically Ill COVID-19 Patients,*" stated:

> Upon further statistical analysis of the critically ill population (hospitalized patients receiving invasive mechanical ventilation (IMV) or ECMO) [in CD12], ***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***.

14. Defendants Continue to Founder with Respect to the BLA Due to Data and Regulatory Vendor Troubles that Result in CytoDyn Losing Access to Leronlimab Clinical Data

211. On April 23, 2021, Pourhassan answered questions about the BLA application during a Proactive Investors interview, stating: "We filed a BLA and we got refuse to file. The refuse[] to file did not say [d]o another [trial]. It said do the data right. Unfortunately, our receptor occupancy was a big problem. And we unfortunately, our dose analysis was not written the way they wanted it. They told us what to do. ***We have done it***."

212. In fact, by that period and after, [redacted]

213. [redacted]

[redacted]

214. A compounding issue [redacted] was CytoDyn's inability to access leronlimab clinical trial data held by Amarex, which Amarex locked and withheld from CytoDyn in the course of a dispute over billing and payments and blame for the RTF letter. [redacted] CytoDyn decided to replace Amarex and attempted to commence a transfer of all study data to new regulatory agents. At the same time, CytoDyn reviewed and challenged numerous unpaid invoices from Amarex for leronlimab clinical trial work, and work on the HIV BLA.

215. In August 2021, after CytoDyn attempted to perform an audit of Amarex's worksites, Amarex refused, and informed CytoDyn that because the Company was in material breach of its contractual payment obligations, all data transfers were suspended. Amarex and CytoDyn engaged in litigation over these issues through the end of 2021, substantially extending CytoDyn's inability to access most of the clinical data on leronlimab that had been generated with respect to both the potential HIV and COVID applications.

216. [redacted]

15. CytoDyn's Latest Efforts to Gain Regulatory Traction With Respect to Leronlimab as a COVID-19 Treatment Fall Flat

217. CytoDyn's COVID-19 indication was faring no better.

218. After Defendants repeatedly touted the CD10 and CD12 results despite the FDA's clear admonishments, on May 17, 2021, the FDA took the highly unusual step of issuing a public statement regarding a drug under pending agency review. In its "Statement on Leronlimab," the FDA referenced Defendants' public statements about the drug, stating, in part:

> CytoDyn has communicated information to the public about the results of these trials [CD10 and CD12]. 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.
>
> * * *
>
> 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. . . . 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 . . . .
>
> 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. . . . None of these analyses met statistical significance when using established and reliable analytical methods that correct for multiple comparisons. . . .

219. Investors reacted to this public refutation of Defendants' claims by the FDA. On May 17, 2021, CytoDyn's stock price fell 27%, $0.76 per share, on heavy trading volume, upon the news.

220. The FDA's Statement on Leronlimab caught Defendants by surprise. [redacted]

[redacted]

[redacted]

221. Seemingly undeterred by the FDA's Statement on Leronlimab, on May 18, 2021, Defendants issued a press release titled, "CytoDyn to Submit Newly Completed Topline Report of CD12 Trial Results to Regulatory Agencies in Multiple Countries including India and Philippines" claiming that the "[f]inalized data analysis shows CD12 trial reached almost all of its major secondary endpoints in a subpopulation (62 patients) of critically ill COVID-19" patients. In other words, [redacted] and one day after the FDA had publicly issued its Statement on Leronlimab, Defendants were claiming to have suddenly met most of the secondary endpoints in the critically ill population subgroup.

222. Thereafter, on a same-day investor conference call, Pourhassan purported "to read everybody the FDA letters, the letter that we got after we asked for emergency use authorization," based on CD12 but in fact read snippets from [redacted] Because Pourhassan chose to publicize the FDA's correspondence regarding EUAs based on the CD12 results during the May 18, 2021 investor call, he had a duty to disclose the material information from the [redacted] letter he omitted from his reading during the call, [redacted]

223. On July 30, 2021, CytoDyn disclosed that it was being investigated by both the SEC and the 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."

224. Nevertheless, [redacted]

16. The Wheels Fall Off for CytoDyn, as Pourhassan is Terminated and the FDA Both Issues a Warning Letter Regarding Leronlimab Misrepresentations and Imposes Clinical Holds with Respect to HIV and COVID-19 Work

225. Defendants' misleading merry-go-round of flawed regulatory submissions, followed by breathless public announcements of these submissions that misrepresented leronlimab's weak claims to efficacy and stalled prospects for FDA approval as a treatment for COVID or HIV, as well as the FDA's negative view of the drug, ground to a halt in early 2022.

226. On January 10, 2022, Cytodyn issued its financial results for 2Q22 on Form 10-Q and scheduled a call with investors for January 13, 2022 following the conclusion of trading that day. However, on the morning of January 13, 2022, the Company unexpectedly cancelled the call and then did not issue any information to investors for 12 days.

227. On January 24, 2022, CytoDyn's BoD terminated Pourhassan and demoted Kelly from his position of Chairman of the BoD. These major changes were disclosed in the first press release since January 13, the following day.

228. Three weeks later, on February 11, 2022, the FDA issued to CytoDyn a nonpublic warning letter regarding Pourhassan's September 22, 2021 "***representations in a promotional context regarding the safety and efficacy of leronlimab, an investigational drug, that ha[d] not been approved or authorized by the FDA and whose safety and efficacy ha[d] not yet been established.***" Referencing the May 17, 2021 Statement on Leronlimab, the FDA concluded that

CytoDyn had ***misbranded*** the drug and, among other things, asked CytoDyn to provide a "comprehensive plan of ***action to disseminate truthful, non-misleading, and complete corrective communication(s)***," addressing the issues raised. The FDA made the warning letter public on February 22, 2022.

229. In response, Defendants scrambled to make corrective communications and remove violative ones. CytoDyn deleted content from its website, provided new banners that clearly identified leronlimab's status as a purely investigational drug, and worked with other content sites to remove presentations and posts CytoDyn had provided or prepared about leronlimab. Proactive Investors, the promotional outlet specifically identified as such by the FDA warning letter, scrubbed all of the videos of its interviews with Pourhassan from its website and YouTube channel.

230. Thereafter, the relevant truth was finally and fully revealed on March 30, 2022. On that date, following the market close, CytoDyn issued a press release entitled, "*CytoDyn Announces Partial Clinical Hold of HIV Program and Full Clinical Hold of COVID-19 Program*" (the "March 30, 2022 Press Release"). The March 30, 2022 Press Release announced that the FDA had "***placed a partial clinical hold on its HIV program and a full clinical hold on its COVID-19 program in the United States***." CytoDyn further disclosed that it was "in the process of reevaluating the timing of its HIV BLA resubmission."

231. According to CytoDyn's Form 10-K dated July 30, 2021, "[a] clinical hold is an order issued by the FDA to the sponsor to . . . suspend an ongoing investigation" that may be issued "[f]ollowing commencement of a clinical trial under an IND." Pursuant to 21 C.F.R. §312.42, the FDA "may place a proposed or ongoing Phase 2 or 3 investigation on clinical hold if it finds that": (i) patients "are or would be exposed to an unreasonable and significant risk of illness or injury"; (ii) "[t]he clinical investigators named in the IND are not qualified"; (iii) "[t]he investigator brochure is misleading, erroneous, or materially incomplete"; or (iv) "[t]he IND does not contain sufficient information required under § 312.23 to assess the risks to subjects of the proposed studies." As further explained in the Company's FY21 Form 10-K, "[f]ollowing the issue of a

clinical hold or a partial clinical hold, a clinical investigation may only resume once the FDA has notified the sponsor that the investigation may proceed." According to CytoDyn, "[t]he FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed or recommence."

232. With the clinical holds in place, any hope for regulatory approval for leronlimab was indefinitely delayed. Defendant Kelly stated on a conference before the market open on March 31, 2022:

> Now, regarding our full clinical hold on the US IND for covid-19 and the partial clinical hold on [the] IND for HIV. There have been no trials ongoing in the United States for COVID-19, we are not enrolling any patients at this time. We are currently not enrolling new patients for HIV and we're closing our long term HIV extension trials after obtaining data in some patients for over six to seven years. The FDA wants aggregated safety data across all indications as our prior C.R.O. was not aggregating safety data. We will correct this and we believe this is a solvable problem. We have contracted with the new pharmacovigilance C.R.O. to move forward, so we expect about eight to 12 week timeline and then we will seek advice from the FDA.

233. As these statements indicate, the FDA issued the clinical holds because [redacted] No further trials were pending or imminent. The marketability of leronlimab in the U.S. was at best a remote hope.

234. On March 31, 2022, CytoDyn's stock price fell 22% on extremely high trading volume.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

235. 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 COVID-19 eINDs; (iii) the Phase 2 Trial (CD10); and (iv) the Phase 2b/3 Trial (CD12).

A. The HIV BLA

1. Statements Concerning the April 27, 2020 and May 11, 2020 HIV BLA Submissions

236. On April 17, 2020, Pourhassan participated in a Wall Street Reporters' Next Super Stock livestream. During the livestream, Pourhassan stated, "Just for everybody's information, I have made it very clear to all of our departments that the BLA needs to be filed next week. ***We have all the information that we needed***. They are all being put together."

237. On April 27, 2020 Defendants 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."

238. 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 . . . ."

239. On April 27, 2020, Defendants 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." The press release stated, "***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."

240. On April 27, 2020, Defendants held a conference call with investors. During the call, in addition to reiterating that the "BLA submission" was "a historical achievement for CytoDyn, Pourhassan stated, "The good news is, ***CytoDyn just filed the full BLA*** last night . . . ."

241. On April 29, 2020, Defendants 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." The press release stated that CytoDyn 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."

242. On April 30, 2020, Defendants issued a press release entitled, "CytoDyn Reports Strong Results from eIND COVID-19 Patients Treated with Leronlimab; Majority of Patients Have Demonstrated Remarkable Recoveries." The press release stated that CytoDyn 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."

243. Market participants reiterated and amplified Defendants' statements. For example, on April 28, 2020, analyst H.C. Wainwright issued a report titled, "HIV Therapy Filing Completed; Leronlimab Decreases COVID-19 Viral Load; Reiterate Buy; Raising PT to $4." The report amplified Defendants' statements concerning the HIV BLA submission, noting that "Leronlimab regulatory filing for HIV infection completed." The report concluded, "in the wake of this derisking event . . . we have decided to lower the discount rate to 12% from 15%," "increased" "[o]ur estimated market value of the firm . . . to $2.4B from $1.7B," and "reiterate our Buy rating while raising the 12-month price target to $4 from $3 per share." Additionally, in an April 30, 2020 article posted to *Seeking Alpha* titled, "CytoDyn: Managing My Position Following BLA Submission And COVID-19 Progress," noted that "CytoDyn finally submitted the final portions of their rolling BLA" and described the HIV BLA as "fully submitted."

244. Defendants' statements set forth above in ¶¶ 236-42 were materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] For example, as set forth in detail in Sections IV.D.2 and IV.D.3, on April 14, 2020, Pourhassan ordered CytoDyn's CRO, Amarex, to submit the HIV BLA

"even if we are short in no matter what portion of whatever it is that we are short" and [redacted]

245. In fact, Defendants knew or were deliberately reckless in not knowing that [redacted] These included, but were not limited to: (i) "critical information and analyses needed to permit substantive clinical, statistical, clinical virology and clinical pharmacology review of [CytoDyn's] proposed dose [of leronlimab]"; (ii) "important variables . . . and analysis files containing the primary efficacy data needed for substantive clinical statistical, clinical virology and clinical pharmacology review of [CytoDyn's proposed dose of leronlimab]"; and (iii) "analyses of subpopulations with regard to effectiveness."

246. More specifically, Defendants knew or were deliberately reckless in not knowing that the HIV BLA did "not include the pertinent information needed for FDA reviewers to perform a substantive review of the [effectiveness of the] dose" the Company selected 700mg despite the provision of "specific advice" by the FDA to Defendants on at least January 22, 2019 and December 16, 2019. Defendants likewise knew or were deliberately reckless in not knowing the HIV BLA did not include "an integrated assessment and detailed summary" supporting CytoDyn's "selected dose" that "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 reflects "data from the 3 doses evaluated in CD03 and for the 350 mg dose evaluated in HTE MDR patients in CD02" must be included, despite the FDA's repeated confirmations that such information must be in a complete BLA submission. [redacted]

[redacted]

247. Additionally, [redacted] Instead, the HIV BLA submission included "only a 2-page 'Rationale for Dose Section' that [wa]s identical to the rationale" provided by CytoDyn with respect to a proposed trial protocol and which the FDA already had informed Defendants was insufficient [redacted] Likewise, despite the fact that "[a]ssessing the safety and effectiveness in subpopulations (sex, age, race, and ethnicity) is an integral part of the BLA review," the HIV BLA "did not include analyses of subpopulations with regard to effectiveness" and was missing "analyses of safety by race or ethnicity."

248. With respect to the safety of the proposed dose, Defendants knew or were deliberately reckless in not knowing that the HIV BLA was "[m]issing [d]ata," "[m]issing [a]nalysis of [c]linical [i]mplications of ADA," "[m]issing ISS [Integrated Summary of Safety] and Summary of Clinical Safety [s]ections," and "[m]issing CRF's and [p]atient [n]arratives." For instance, the "Summary of Clinical Safety" section in the HIV BLA merely "re-list[ed] the SAEs, instead of addressing the events that lead to drug discontinuation . . . which is a necessary component of a BLA," "[n]o information [wa]s provided in the section, 'Adverse Events Leading to Drug Interruption,'" and the section "titled 'Other Significant Adverse Events,'" was "actually a repeated assessment of SAEs" instead of "AEs that led to treatment discontinuation." As set forth above in Section IV.C, Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted]

249. Moreover, despite the FDA's specific request in January 2019 and again in December 2019 that comprehensive "CCR5 receptor occupancy data for the 350 mg, 525 mg and 700 mg doses" be "submit[ted]" with CytoDyn's HIV BLA submission, Defendants knew or were deliberately reckless in not knowing that the HIV BLA "include[d] only representative data from 525 mg and 700 mg in the receptor occupancy report." In fact, the "Receptor Occupancy Datasets [were] Missing" from the HIV BLA altogether and Defendants knew or were deliberately reckless in not knowing that at the time the HIV BLA was filed, [redacted]

250. Additionally, Defendants knew or were deliberately reckless in not knowing that, [redacted] these reports were "not included" in the HIV BLA. Further, despite the importance of population PK analyses "to ensure the safe and effective use of drugs," and CytoDyn's prior assertions in January 2019 of "plans to use studies CD02, CD03, and CD06 . . . for the Pop PK" analysis, the HIV BLA included the "Submission of [an] Unagreed Upon" Pop PK analysis based on data from CD02, CD03, and Study 2101 "without a clear rationale for including the results from study 2101 and excluding the results from trial CD06." Defendants likewise knew or were deliberately reckless in not knowing that HIV BLA likewise did not include "Clinical Virology Report[s]" for the CD02 and CD03

studies, an "integrated summary of clinical pharmacology results," and "PK or PD results from any of the clinical studies," and "critical elements" in the "Statistical," "Safety," and "Virology Resistance" datasets were "Missing." [redacted] as set forth above in Section IV.C.

251. Finally, Defendants knew or were deliberately reckless in not knowing that the HIV BLA was not complete [redacted]

252. Accordingly, Defendants' statements set forth above in ¶¶ 236-42 asserting that CytoDyn had "all the information that [it] needed" for the HIV BLA, the HIV BLA was "complete" and/or "completed," or that the "full" HIV BLA had been filed were materially false and misleading, omitted material facts, or otherwise lacked a reasonable basis when made.

253. Thereafter, on May 13, 2020, Defendants issued a press release entitled, "CytoDyn Completed Submission of All Remaining Parts of Biologics License Application ("BLA") on May 11, 2020." The press release "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."

254. On May 15, 2020, during an interview with Proactive Investors paid for by CytoDyn, Pourhassan described the HIV BLA as a "***complete package***."

255. On July 4, 2020, Pourhassan participated in a discussion with Dr. Been. During the discussion, 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 [said] 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.)

256. Analysts repeated and amplified Defendants' statements. For instance, in a May 13, 2020 report titled "Biologics License Application Fully Completed; Reiterate Buy," H.C. Wainwright stated: "**Biologics License Application now officially complete.** CytoDyn has confirmed that on May 11, 2020, it submitted all remaining parts of the Biologics License Application (BLA)" and "informed the FDA it had submitted a complete BLA for rolling review." (Emphasis in original). In a subsequent May 27, 2020 report, H.C. Wainwright reiterated, "**Regulatory submission completed**. Earlier this month, CytoDyn confirmed that it had submitted all remaining parts of the Biologics License Application (BLA)" and "informed the FDA it had submitted a complete BLA for rolling review." (Emphasis in original).

257. Defendants' statements set forth above in ¶¶ 236-42 and 253-55 were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] For example, as set forth in detail in Section IV.D.2 and IV.D.3, on April 14, 2020, Pourhassan ordered CytoDyn's CRO, Amarex, to submit the HIV BLA "even if we are short in no matter what portion of whatever it is that we are short" [redacted] As set forth above in ¶¶ 245-51, Defendants knew or were deliberately reckless in not knowing that specific

data, information, summaries, and analyses the FDA had expressly told Defendants must be included as part of CytoDyn's BLA submission in 2018 and 2019 were not included in the April 27, 2020 submission.

2. Statements Concerning the RTF Letter and the HIV BLA Resubmission

258. On July 13, 2020, Defendants issued a pre-market press release entitled, "Update on HIV-BLA-PDUFA: ***FDA requested more information to complete a 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 the agency's suggestion." The press release stated that CytoDyn:

> [P]reviously announced it submitted all remaining parts of its BLA for leronlimab on May 11, 2020. Pursuant to FDA guidelines, CytoDyn informed the FDA it had submitted a complete BLA for rolling review. In its comments on May 13, CytoDyn stated as a next step after receiving the BLA, the FDA would start reviewing the BLA for completeness and would make a filing decision. 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.

259. The press release further stated that CytoDyn "intends to request a Type A meeting with the FDA to discuss its request for additional information. The FDA's request does not require any additional clinical trials to be conducted, rather the Company will conduct additional analysis of completed trials."

260. The same press release also quoted Pourhassan as stating, "We are 100% committed and confident we can provide the necessary information to the FDA as soon as possible. ***No additional trials will be required*** and ***all the information the FDA has requested is obtainable***."

261. Defendants also held a conference call with investors after the conclusion of trading on July 13, 2020. During the call, Pourhassan claimed that the "***BLA included information about [the] CD03 trial for the safety portion of the BLA.***" Pourhassan likewise claimed that "***CytoDyn felt the [BLA] was completed for the FDA to provide the PDUFA date.***"

262. On the same call, Pourhassan also stated: "We are thankful that the information needed does not require any more trials, and it is simply getting the information that the agency

requested with the detail that they require." Pourhassan further stated: "the information requested by the FDA is mainly for one module, the clinical, and a few minor points about manufacturing."

263. Following Pourhassan's statements, Dr. Dhody stated the following on behalf of CytoDyn:

> One of the critical components for this recent communication with FDA is related with the fact that we are seeking an approval for a 700 milligram dose that was tested in the monotherapy indication under our ongoing CD03 trial, whereas the heavily treatment experience, the indication for which we are seeking an approval, was done on 350 milligram dose.
>
> As you mentioned in your previous comments, that FDA has recommended us to consider 700 milligram dose for a heavily treatment experience based on the results from an ongoing trial. Now, because we are getting an approval for a 700 milligram dose, ***that FDA would want an additional analysis to be performed on an ongoing CD03 trial. And that is the majority of the comments that FDA has — that the FDA requested some of the information from an ongoing trial.*** The CD03, which has tested a 350 milligram dose, as well as 525 and 700. ***And FDA has recommended that we do an integrated assessment of the efficacy, as well as safety, all the exposure-related analysis, receptor occupancy, and [bioanalytical] analysis***.

264. Additionally, in response to a question concerning whether "the FDA wanted an integrated analysis of the efficacy and safety data of leronlimab at 350 milligram, 500 milligram and 700 milligram from the monotherapy CD03 trial," Dr. Dhody stated on behalf of CytoDyn:

> So that is correct. As we said, one of the biggest — this is been a groundbreaking approach that FDA has not used before, in which they are considering to approve a product on a higher dose [than] that has been tested for an indication. So as you know, the approval that we are asking for is heavily treatment experience population, which was tested with 350 milligram dose.
>
> However, the FDA is willing to give an approval for leronlimab for a 700 milligram dose that has not been tested in the heavily treatment experience population. But to do that, for the FDA to give us an approval for 700 milligram dose, ***they would want us to provide an analysis of dose exposure at 350, 525 and 700, and that can be done. It is not that it is not doable. The challenge is always about the trial that is ongoing. Now that we have completed the treatment with [three] dose levels in our monotherapy study, we can use the data from monotherapy to provide that additional information that the agency is requesting for at this time.***

(First alteration in original).

265. In response to the same question, Pourhassan stated, "we thought [about] the issue between 700, 350 and 525 comparison. If there's any more question [it] will be under review section of the [HIV BLA], which is usually six months or ten months standard [after the FDA accepted the HIV BLA for filing]." (First alteration in original). In other words, Pourhassan asserted that CytoDyn "thought" that "issue[s]" with the dosage "comparison" would arise after the FDA accepted the HIV BLA for filing or, "we thought that would be there. . . ."

266. During the same call, in response to a question concerning whether "this would be the first time that the FDA would approve[] a drug at [350] milligram for heavily treated patients, but without actually having heavily treated patients exposed to 700 milligram — as long as you're providing that data from monotherapy treatment group?", Dr. Dhody stated:

> Yeah, that is correct. So that brings us that, although you can say that the trial for the CD02 was completed, and it's just because of this additional higher-dose level data, that is still being ongoing at this point of time, that leads us to this situation where we have to do more in-depth analysis for an ongoing clinical trial. But we are definitely equipped, and we are planning to get this information back to FDA as quickly as we can.

267. Market participants repeated and amplified Defendants' statements. For instance, on July 14, 2020, analyst H.C. Wainwright issued a report reiterating Defendants' statements. For instance, H.C. Wainwright's report stated, "Management noted that the FDA does not require any further clinical trials to be conducted, but that additional analysis of completed trials needs to be performed." The same report further stated, "The agency is ***now*** asking CytoDyn to perform an integrated analysis with data from the CD03 trial. Since the CD03 trial has already completed enrollment and treatment of roughly 595 subjects (with the last patient treatment having occurred in June 2020), including 130 subjects exposed to the 700mg dose, we believe the analysis could be completed in a reasonable time frame." The report also noted that "The CD03 trial data is slated to be included in the BLA filing and was not part of the original application." The report concluded, "We believe CytoDyn should be able to resubmit the BLA in a timely manner and eventually secure FDA approval for leronlimab in HIV." H.C. Wainwright repeated similar assertions in a subsequent July 16, 2020 report.

268. Likewise, in a July 16, 2020 article posted to *Seeking Alpha* titled, "CytoDyn's BLA Blues" the author reported that Pourhassan "advised that the RTF [letter] set out complete instructions on the information required for CytoDyn to complete its BLA" and that "all the requested information can be obtained by CytoDyn." The article further stated, "At the FDA's suggestion, the BLA seeks FDA approval for leronlimab dosed at 700 mg, supported by safety data from CD03. . . . The RTF [letter] is looking for a detailed and integrated assessment of the data that goes beyond the data presented to this point." The article continued, "Dr. Dhody expressed no reservations concerning availability of data requested by the FDA. The reason this has been a point of difficulty has been because CD03 is an ongoing trial. Now however it has progress to the point that it is no longer a concern . . .."

269. Defendants' statements set forth above in ¶¶ 258-66 were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] As set forth above in ¶¶ 245-51 many of the deficiencies identified by the FDA in the RTF letter were [redacted] As such, Defendants' statements immediately following the public disclosure of the existence of the RTF letter created a misleading impression with respect to (i) what the FDA required the Company to submit [redacted] with any BLA submission prior to April 2020 [redacted] (ii) the nature, scope, and extent of the deficiencies identified in the RTF letter; and (iii) [redacted]

270. More specifically, Defendants' statements set forth above in ¶¶ 258-66 that, per the FDA, the "BLA does not contain certain information needed to complete a substantive review," and that the FDA required more or additional information, analyses, or detail than what CytoDyn

provided in the original HIV BLA submissions in April and May 2020 or that the FDA was requiring effectively an update from an ongoing clinical trial were materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] *See supra* ¶¶ 245-51. Accordingly, these statements leave the misleading impression that the RTF letter was the first time that the FDA had requested this information [redacted]

271. Moreover, Defendants' statements set forth above in ¶ 263 that "[t]he FDA has recommended that we do an integrated assessment of the efficacy, as well as safety, all the exposure-related analysis, receptor occupancy, and [bioanalytical] analysis" were materially false and misleading, omitted material information, or lacked a reasonable basis when made for the same reasons.

272. Additionally, Defendants' statements set forth above in ¶¶ 264-65 that the FDA "want[ed]" CytoDyn "to provide an analysis of dose exposure at 350, 525 and 700," and that they "thought" that "issue[s]" or "[i]f there's any more question[s]" about the "700, 350 and 525 [dosage] comparison" it would "be under [the] review section of the [HIV BLA]," were materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted]

273. Moreover, Defendants' statements set forth above in ¶¶ 258-60 that "[n]o additional trials [are] required," the RTF "does not require any additional clinical trials to be conducted," and "the information needed does not require any more trials" were materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that neither the RTF Letter [redacted] had made any assurances with respect to the need for additional trials in support of the HIV BLA. Simply put, the RTF letter could not make any such assurances because it reflected the FDA's rejection of the entire HIV BLA submission prior to any substantive review of the information, data, analyses, and summaries contained therein.

274. In the lead-up to the filing of the HIV BLA, [redacted]

[redacted]

275. Defendants also knew or were deliberately reckless in not knowing that one of the main ways the receptor occupancy data deficiencies identified in the RTF letter could be satisfactorily addressed [redacted] the FDA rejected the receptor occupancy assay CytoDyn utilized to generate the representative data for the 525 mg and 700 mg doses in the RTF letter, Defendants knew or were deliberately reckless in not knowing that, [redacted] As such, Defendants' claim that no additional trials were required was materially false and misleading, omitted material information, or lacked a reasonable basis when made.

276. On August 14, 2020, CytoDyn filed with the SEC its results for fiscal year 2020 on Form 10-K ("FY20 Form 10-K"). Defendants Pourhassan, Mulholland and Kelly signed the FY20 Form 10-K and Pourhassan and Mulholland certified the veracity of its contents. The FY20 Form 10-K stated, in relevant part, "We filed with the FDA the clinical, along with the Chemistry,

Manufacturing, and Controls ('CMC') portions of the BLA April and May of 2020. In July 2020, we received a Refusal to File letter from the FDA regarding the BLA filing, and requested a Type A meeting to discuss ***the FDA's request for additional information***."

277. The FY20 Form 10-K also stated:

> The Company filed a 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. In July 2020, the FDA issued a Refusal to File the BLA stating that it needed additional information to complete its substantive review. ***The FDA's request requires additional analysis of completed trials and does not require any additional clinical trials to be conducted***, and the Company is working diligently to provide the information required by the FDA in order to resubmit its BLA for this combination therapy.

278. With respect to CytoDyn's inventory accounting, the FY20 Form 10-K stated:

> The Company's inventory as of May 31, 2020 and May 31, 2019 was $19,146,678 and $0, respectively. Inventory as of May 31, 2020 consisted of raw materials purchased for use in the commercial manufacturing of pre-launch inventories of leronlimab 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 ***material uncertainties related to the ultimate regulatory approval of leronlimab for commercial sale have been significantly reduced based on positive data from Phase 3 clinical trial results, and information gathered from pre-filing meetings with the FDA for the BLA.*** The BLA was initially submitted with the FDA in April 2020 and ***the BLA submission was completed on May 11, 2020.*** In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA filing ***requesting additional information***, and the Company has requested a Type A meeting to discuss ***the FDA's request for additional information***, which the Company expects will be resolved on a timely basis during calendar year 2020.

279. The FY20 Form 10-K likewise stated:

> In July 2020, the Company received a Refusal to File letter from the FDA . . . . The FDA's request does not require any additional clinical trials to be conducted, rather that the Company conduct specifically requested additional analysis of the completed trials data. The Company has scheduled a Type A meeting to discuss the FDA's request for additional information. The Company expects to resubmit the BLA with the additionally required data by the end of calendar year 2020.

280. On August 20, 2020, Pourhassan participated in a Proactive Investors interview paid for by CytoDyn. During the interview, Pourhassan stated:

> So Type A meeting was a refuse to file letter that we got and we tried to explain to everybody. ***We didn't, we were not given directions to do another clinical trial.*** So that's always a great thing. ***All we have to do is to to [sic] provide the information that we now have in the form that the FDA requests. . . . We have the data.***

281. On September 2, 2020, Defendants held a conference call with investors. During the call, Pourhassan stated:

> The FDA just got back with us yesterday with all their answers to our questions. . . .
>
> [The] FDA also offered and I'm going to read this part from the letter that they send us. They said, "To ensure that your revised BLA include the personal information needed for FDA reviewers to prove -- to perform a substantive review of the dose you have selected, the agency is willing to perform a multidisciplinary review of your revised dose rationale and integrated assessment of supportive safety efficacy, PK and PD data prior to the submission of your revised BLA. If you choose to take advantage of this offer, please provide us at least 30 days to review the submission and allow yourself sufficient time to revise the BLA in response to our recommendation, if needed."
>
> [But] that's a very beautiful thing we're getting . . . .

282. Defendants' statements set forth above in ¶¶ 276-81 were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] As set forth above in ¶¶ 245-51 and 274-75 many of the deficiencies identified by the FDA in the RTF letter [redacted] As such, Defendants' statements immediately following the public disclosure of the existence of the RTF letter created a misleading impression with respect to (i) what the FDA required the Company to submit [redacted] with any BLA submission prior to April 2020 [redacted] (ii) the nature, scope, and extent of the deficiencies identified in the RTF letter; and (iii) the fact that in many instances, [redacted]

283. More specifically, Defendants' statements set forth above in ¶¶ 276-81 that the FDA required more or additional information, analyses, or detail than what CytoDyn provided in the original HIV BLA submissions in April and May 2020 or that the FDA was requiring effectively an update from an ongoing clinical trial were materially false and misleading, omitted

material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] *See supra* ¶¶ 245-51 and 274-75. Accordingly, these statements leave the misleading impression that the RTF letter was [redacted]

284. Moreover, Defendants' statements set forth above in ¶¶ 277, 280 that "[t]he FDA's request does not require any additional clinical trials to be conducted" and "we were not given directions to do another clinical trial" were materially false and misleading, omitted material information or lacked a reasonable basis when made for the same reasons as are set forth above in ¶¶ 282-83.

285. Additionally, Defendants' statement set forth above in ¶ 280 that "[a]ll we have to do is . . . provide the information we now have in the form that the FDA requests. . . . We have the data," was materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, [redacted] Accordingly, and contrary to Defendants' claim "We have the data," [redacted] following the imposition of the partial clinical hold on the HIV IND on or around March 30, 2022, [redacted]

286. This statement also is materially false and misleading, omitted material information, or lacked a reasonable basis because Defendants knew or were deliberately reckless

in not knowing that, at the time, and as Defendants subsequently admitted on March 30, 2022, CytoDyn did not have aggregated safety data because the Company's CRO, Amarex, was not aggregating safety data.

287. Finally, Defendants' statement set forth above in ¶ 278 that "material uncertainties related to the ultimate regulatory approval of leronlimab . . . have been significantly reduced based on positive data from Phase 3 clinical trial results, and information gathered from pre-filing meetings with the FDA for the BLA" was materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in disregarding that, contrary to their sole internal justification for this statement—that the "FDA[] has concluded that leronlimab has a strong safety and efficacy profile"—[redacted] As such, Defendants' claim that "material uncertainties" concerning the approval of leronlimab had been significantly reduced was materially false and misleading, omitted material information, or lacked a reasonable basis when made.

288. On September 16, 2020, Defendants held a conference call with investors. During the call, Dr. Dhody stated on behalf of CytoDyn, "So we had a meeting with the FDA on September

8. ***The purpose of this meeting is to come to an agreement with the agency for the submission of efficacy data to support 700 milligram dose."*** Dr. Dhody further described the discussion at the meeting, claiming that the "***FDA wants to see a data from an ongoing monotherapy study to support the efficacy, not only the safety, but also the efficacy of 700 milligram dose from the CD03. We have come to a complete agreement with the agency and the terms of what level of information that needs to be provided from other current ongoing study.***"

289. With respect to the data discussed at the meeting with the FDA, Dr. Dhody further stated: "I wanted to make it clear that from our standpoint . . . we have all the . . . information that is needed to be submitted to agency. . . . [W]e have all patients in the 700 milligram dose have completed their treatment. So we have all available data at this point of time . . . ."

290. On September 23, 2020, Pourhassan participated in a discussion with Dr. Been. During the discussion, Pourhassan stated: "In regards to HIV . . . . Unfortunately, we had refused to file a letter, ***but that refused to fund it says we need more data that you have. But you didn't have it been submitted, because the trial that they asked for safety was not completed.*** With that said, ***at least we have all the data. . . . ."***

291. On October 9, 2020, CytoDyn filed a Form 10-Q for the fiscal quarter ended August 31, 2020 ("1Q21 Form 10-Q"). The 1Q21 Form 10-Q was signed and certified by Pourhassan and Mulholland. In the 1Q21 Form 10-Q, CytoDyn stated:

> In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA submission in April and May of 2020 for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients. The FDA informed the Company its BLA did not contain certain information needed to complete a substantive review and therefore, the FDA would not file the BLA. ***The FDA's request does not require any additional clinical trials to be conducted, rather that the Company conduct specifically requested additional analysis of the completed trials data.*** The Company requested a Type A meeting to discuss ***the FDA's request for additional information.*** The FDA did not schedule a Type A meeting, but requested the Company submit all questions regarding the filing in writing. In September 2020, the Company submitted questions to the FDA, received written responses, and held a telephonic meeting with the FDA to obtain further clarity ***on what additional information was required with respect to the BLA filing.*** . . .

292. The 1Q21 Form 10-Q also stated:

> We subsequently filed with the FDA the clinical, along with the Chemistry, Manufacturing, and Controls ("CMC") portions of the BLA April 2020, ***and completed our submission with the FDA on May 11, 2020***. In July 2020, we received a Refusal to File letter from the FDA regarding the BLA filing, and requested a Type A meeting with the FDA to discuss ***the FDA's request for additional information.*** The FDA did not schedule a Type A meeting, but requested the Company submit all questions regarding the filing in writing. In September 2020, we submitted our questions to the FDA, received written responses, and held a telephonic meeting with the FDA to obtain further clarity ***on what additional information was required with respect to our BLA filing.*** We understand that ***the FDA's [sic] is requiring additional analysis of completed trials and results . . . .***

293. The 1Q21 Form 10-Q further stated:

> The Company's inventory as of August 31, 2020 and May 31, 2020 was $58.5 million and $19.1 million, respectively. Inventory as of August 31, 2020 consisted of raw materials purchased and work in progress inventory related to the commercial production of pre-launch inventories of leronlimab 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 ***material uncertainties related to the ultimate regulatory approval of leronlimab for commercial sale have been significantly reduced based on positive data from the Phase 3 clinical trial results, and information gathered from pre-filing meetings with the FDA for the BLA.*** The BLA was initially submitted with the FDA in April 2020 and ***the BLA submission was completed on May 11, 2020.*** In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA filing ***requesting additional information***, and the Company requested a Type A meeting to discuss ***the FDA's request for additional information.*** The FDA did not schedule a Type A meeting, but requested the Company submit all questions regarding the filing in writing. In September 2020, the Company submitted its questions to the FDA, received written responses, and held a telephonic meeting with the FDA to obtain further clarity ***on what additional information was required with respect to the BLA filing.***

294. On April 7, 2021, Defendants held a conference call for investors. During the call, in response to a question about the RTF letter, Pourhassan stated:

> So the big news for me was, ***there was no additional clinical trials, just get the data in the right format,*** and we're doing that. The hard part of our BLA was that we were doing a small clinical trial in combination therapy, ***that was in enough patients for safety, so the FDA was kind enough to allow us to pull data from another trial.***

295. During the same call, Dr. Recknor stated:

> Actually, the dose justification is the issue with the BLA and, in particular, the receptor occupancy. And Nader, I think it's important to note that ***the prior assay was the thing that was in question***, which was the same thing that we saw on the CD10 trials, the receptor occupancy assay just . . . the FDA had a lot of questions with it. So, we'll be repeating that. With the solid assay, we have two different companies working with us on that. ***But the dose distribution alone from the standpoint of the viral load is very impressive. At the 700 dose its T-value is statistically significant, 0.006 at the 700 dose***, so we feel very confident just ***with the data that we have, inclusive of the receptor occupancy*** that we can

> make the argument. ***We are also doing receptor occupancy, though, in the extension patients that we have ongoing***.

(Ellipsis in original).

296. On April 23, 2021, Pourhassan participated in a Proactive Investors interview paid for by CytoDyn. During the interview, Pourhassan stated: "We filed a BLA and we got refuse to file. ***The refuse to file did not say do another trial. It said do the data right.*** Unfortunately, our receptor occupancy was a big problem. And we unfortunately, on ***dose analysis was not written the way they wanted it.*** They told us what to do. ***We have done it***."

297. On May 3, 2021, CytoDyn issued a press release titled, "CytoDyn HIV Indication Update: Leronlimab HIV Extension Arm Nearing 7 Years with Continued Excellent Safety Results." The press release quoted Dr. Recknor as follows: "***CytoDyn has gained tremendous insight in the safety of Vyrologix through extension of their three core HIV trials.*** There have been 66 patients from the original trials still receiving Vyrologix in an open label design with an exposure range of 4-7 years. ***No significant adverse safety issues reported.***"

298. On May 5, 2021, Defendants held a conference call with investors. During the call, Defendant Pourhassan stated: "We were very surprised and caught off guard with everything happened with the BLA where 350 milligram and 525 milligram and 700 milligram made things complicated."

299. On June 21, 2021, Defendants held a conference call with investors. During the call, Dr. Recknor stated:

> The first thing that we've done is really improved the communication with the FDA and one of those was asking about the receptor occupancy study, talking about the justification and because of this involvement with the FDA, we are submitting the key part of this [BLA] that is held this thing up on, ***it's not that there wasn't a statistical finding in CD0 2. It's not that CD0 3 didn't look great, it's what dose out of these 3, 350, 525 and 700 would -- do you think works fast.***
>
> And at this point, now ***we have 48-week data, very excited about it In addition to the 24-week data*** and we'll be submitting the dose justification report in a draft form to the FDA and they've made it available to go ahead and give us comments on that to help us with the BLA. So it's a very good working relationship and we're encouraged by that.

300. On July 1, 2021, Defendants issued a press release titled, "CytoDyn Submits Dose Justification Report to FDA to Begin Overcoming Deficiencies in its BLA for HIV." The press release stated that CytoDyn "has submitted a dose justification report to the U.S. Food and Drug Administration" "a key component for the BLA" which "***includes receptor occupancy analysis, among other factors, to determine the optimal marketed dose for leronlimab.***"

301. On July 22, 2021, CytoDyn held a conference call with investors. During the call, Dr. Recknor stated:

> What we did is we took the biggest problem, I guess, with the BLA. And just wanted to turn things around and submit that and take care of that first with the FDA. And so in talking with the FDA in the past, there were issues with receptor occupancy assay. And so we submitted on this draft to them about our plan for receptor occupancy, and they agreed, and we're proceeding. And we're thrilled.
>
> This is one huge obstacle that we now have overcome.

302. On August 16, 2021, Pourhassan participated in a Proactive Investors interview paid for by CytoDyn. During the interview, Pourhassan stated:

> So when we had our BLA ready to go several months ago, we had a problem. The problem was we had changed our dosage from 350 [mg] to the higher dose of 700 mg. FDA had asked for a lot of information, including receptor occupancy tests. We had submitted our full BLA and got refuse to file, which is a serious thing to get from FDA. We took that very seriously, ***FDA said, however, you don't have to do any other trial.*** You just have to give us what we're asking for and you keep not doing that. So with that said, they ask us to make sure that we have a receptor occupancy test that works because the one that we sent to them was just absolutely not to their standard. ***We have done that with the dosage finding and receptor occupancy test and getting the results within 30 days that, hey, this looks OK.***

303. The statements set forth in ¶¶ 288-302 were materially false and misleading when made because Defendants knew or were deliberately reckless in not knowing that [redacted] As set forth above in ¶¶ 282-83 and 287 many of the deficiencies identified by the FDA in the RTF letter were well known to Defendants prior to original HIV BLA submission. As such, Defendants' statements immediately following the public disclosure of the

existence of the RTF letter created a misleading impression with respect to (i) what the FDA required the Company to submit [redacted] with any BLA submission prior to April 2020 [redacted] (ii) the nature, scope, and extent of the deficiencies identified in the RTF letter; and (iii) the fact that in many instances, [redacted]

304. More specifically, Defendants' statements set forth above in ¶¶ 288-302 that the FDA required more or additional information, analyses, or detail than what CytoDyn provided in the original HIV BLA submissions in April and May 2020 or that the FDA was requiring effectively an update from an ongoing clinical trial were materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] *See supra* ¶¶ 282-83 and 287. Likewise, Defendants' statements set forth above in ¶ 288 that they had "have come to a complete agreement with the agency" or "come to an agreement with the agency for the submission of efficacy data to support [the] 700 milligram dose" were materially false and misleading, omitted material facts, or lacked a reasonable basis [redacted]

305. Defendants' statements set forth above in ¶¶ 294, 297 that there were enough "patients for safety, so the FDA was kind enough to allow us to pull data from another trial" and

"CytoDyn has gained tremendous insight in the safety of [leronlimab] through extension of their three core HIV trials," with "[n]o significant adverse safety issues reported" were materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, [redacted] These statements also are materially false and misleading, omitted material information, or lacked a reasonable basis because Defendants knew or were deliberately reckless in not knowing that, at the time of this statement, and as Defendants subsequently admitted on March 30, 2022, CytoDyn did not have aggregated safety data because the Company's CRO, Amarex, was not aggregating safety data.

306. Additionally, Defendants' statements set forth above in ¶ 298 that "[w]e were very surprised and caught off guard with everything [that] happened with the BLA where 350 milligram and 525 milligram and 700 milligram made things complicated" were materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted]

307. Moreover, Defendants' statements set forth above in ¶¶ 291 and 302 that "[t]he FDA's request does not require any additional clinical trials to be conducted" and "FDA said . . . you don't have to do any other trial" were materially false and misleading, omitted material information or lacked a reasonable basis when made for the same reasons as are set forth above in ¶¶ 282-83.

308. Additionally, Defendants' statement set forth above in ¶¶ 289-90 with respect to the dose justification report and that "we have all the . . . information that is needed to be submitted to agency," "we have all available data at this point of time," "that refused to file it says we need more data that you have," "at least we have all the data" and "with the data that we have, inclusive of receptor occupancy," were materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, [redacted]

309. This statement also is materially false and misleading, omitted material information, or lacked a reasonable basis because Defendants knew or were deliberately reckless

in not knowing that, at the time, and as Defendants subsequently admitted on March 30, 2022, CytoDyn did not have aggregated safety data because the Company's CRO, Amarex, was not aggregating safety data.

310. Further, for the same reasons, Defendants' statements set forth above in ¶¶ 296 and 302 that the "dose analysis was not written the way they wanted it. . . . We have done it," and they had given the FDA what they wanted "with the dosage finding and receptor occupancy test" and "overcome" the receptor occupancy issues were materially false and misleading, omitted material information, or lacked a reasonable basis when made. [redacted]

311. Finally, Defendants' statements set forth above in ¶ 293 that "material uncertainties related to the ultimate regulatory approval of leronlimab . . . have been significantly reduced based on positive data from Phase 3 clinical trial results, and information gathered from pre-filing meetings with the FDA for the BLA" was materially false and misleading, omitted material information, or lacked a reasonable basis when made for the same reasons as are set forth above in ¶¶ 282-83.

B. COVID-19

1. Statements Concerning eIND Applications and Resulting "Data"

312. On March 27, 2020, Defendants issued back-to-back press releases. The first press release was titled, "CytoDyn Files FDA-Suggested Modifications to IND and Protocol for Phase 2 Clinical Trial for COVID-19 Patients with Mild to Moderate Indications and a Second Randomized Protocol for All COVID-19 Patients in Severe Condition Will be Filed Next Week ***per FDA Recommendation.***" In that press release, Defendants stated, "***the FDA suggested the Company file a second randomized protocol for all COVID-19 patients in severe condition, so as to preclude each physician from filing an emergency IND for every patient to be treated with***

leronlimab." The same press release also quoted Pourhassan as follows: "We will now also immediately file a second trial protocol, ***per the FDA's suggestion***, for severely ill COVID-19 patients."

313. The second press release was titled, "Leronlimab Used in Seven Patients with Severe COVID-19 Demonstrated Promise with Two Intubated Patients in ICU, Removed from ICU and Extubated with Reduced Pulmonary Inflammation." According the second press release, "**IncellDx's evaluation of test results from the first four patients *suggests immunological benefit within three days following treatment with leronlimab on all four*** patients." (Some emphasis in original).

314. Also on March 27, 2020, Pourhassan and Dr. Patterson participated in an interview conducted by Proactive Investors and paid for by CytoDyn. During the interview, Pourhassan stated:

> [W]e announced so far today two out of seven patient extubated. . . . But we needed to get an analysis of what's happening with the cytokine storm. So Dr. Bruce Patterson worked with his whole team overnight, two nights in a row, and we got the blood sample at day zero and then day three of four patients . . . . And then he called all of us at midnight, says, "guys, ***the cytokine storm [data] is really strong." Obviously, FDA has . . . talked to us about filing a protocol for that***.

315. When asked his "professional opinion" as to whether leronlimab "could . . . potentially be a treatment for the coronavirus," Dr. Patterson stated, on behalf of CytoDyn: "***Absolutely*** . . . I think ***we've already shown data on four patients already that and as [Nader] suggested, two of which have been extubated, that this can be a therapy, especially in the severe cases*** . . . ."

316. When asked about "the latest on what the FDA is saying in terms of filing a protocol here," Pourhassan stated:

> All these studies that we did in the last five years is paying dividends because now we're able to be able to take that data and say to the FDA, here's our data. If we didn't not [sic] have that, we could not be in the position we are with coronavirus. So the FDA has given us some modifications to our phase two protocol. This is for [mild] and moderate patients who [are] not severe. And then when perhaps the results of [t]hese patients were coming

> out. [t]he FDA has told us that as of yesterday that we would also like you to do another protocol that would treat severe patient. . . .

317. On March 31, 2020, Pourhassan answered questions as part of an interview conducted by Proactive Investors and paid for by CytoDyn. During the interview, Pourhassan stated:

> So it's very important for everybody to understand that this Phase 2 that we just got green light, safe to proceed, the letter from FDA is a major milestone for us because usually you have to go through pre-IND, which is a 60 day, and then IND, which is 30 days ***due to, I believe, because we had very strong results in a New York hospitals with 10 patients that we enrolled and the first four patient results showing immunological benefit. The FDA was very gracious to us, gave us Phase 2 green light.*** They had a lot of modification. Obviously, they wanted to make sure we are on the same page and ***we made those modifications***. And everybody should realize when you have an open IND acceptance of an IND for a given indications, then if you submit extra protocol for different indications that same disease, you don't have to have any 30 day waiting. ***And the FDA had asked us beside this protocol, which is for [COVID] patients with mild or moderate condition, they said also send in a protocol, which is a Phase 3 for severe patient population.*** So we also are working on that . . . . Now that if we inject patients with severe condition, what we seen in the early results is patients, some of the patients were able to get off of the ICU, get off of the . . . ventilator and also one of the patients now we know is going to be released from the hospital. ***Now that's major results.*** . . . So we're very, very happy that ***the FDA has worked with us so quickly and able to expedite this since there was some positive results***.

318. On April 1, 2020, Pourhassan participated in an interview conducted by Yahoo! Finance. During the interview, Pourhassan described the results from the first four eIND patients as "***spectacular***" and as "***a very strong result for us***" and claimed that "[t]he results . . . from the first four patients" demonstrated an "***immunological benefit***" from the use of leronlimab. Pourhassan further stated, "***that was a very big start for us with the FDA when we said that our scientists believe we can stop cytokine storm*** . . . ."

319. On April 2, 2020, Defendants issued a press release titled, "Treatment with CytoDyn's Leronlimab Indicates Significant Trend Toward Immunological Restoration in Severely Ill COVID-19 Patients" ("April 2, 2020 Press Release"). The April 2, 2020 Press Release stated, "***the three-day effect of leronlimab in eight severely ill COVID-19 patients demonstrated a significant improvement in several important immunological bio-markers.***"

320. Also on April 2, 2020, Pourhassan participated in two interviews. The first interview was a Proactive Investors interview paid for by CytoDyn. During the Proactive Investors interview, Pourhassan stated, "[t]his is the results from the beginning and the results at the three day. All eight patients ***had immunological benefit***" from leronlimab.

321. The second interview was with TD Ameritrade. During the TD Ameritrade interview, Pourhassan claimed that "the results" from "the first eight patients" "***show . . . the immunological benefit for all patients***" and that "***all eight had the immunological benefit***" from leronlimab.

322. Market participants repeated and emphasized Defendants' statements. For example, in a March 28, 2020 article posted to *Seeking Alpha* titled, "CytoDyn May Be One of the First Biotechs to Have a Drug That Helps Against COVID-19," the author noted that CytoDyn had "revealed the initial results of the use of its drug" to treat COVID-19 and concluded, "[t]his is very early evidence for the use of this drug in infectious disease . . . . Investors may wish to pay attention since there are so few medications which have shown this kind of promise against [COVID]-19." Likewise, H.C. Wainwright issued a March 30, 2020 report titled, "Promising Preliminary Results in COVID-19 Patients; Reiterate Buy." Under the headline, "**Leronlimab reduces cytokine storm and extubates COVID-19 patients**," the report stated, "Last Friday, CytoDyn announced that four patients infected with COVID-19 . . . had shown positive improvement in their immune profiles following three days of treatment with leronlimab. . . . In our view, these preliminary data demonstrate the potential of leronlimab to help hospitalized COVID-19 patients recover from pulmonary inflammation that drives mortality and the need for ventilators . . . ." (Emphasis in original). The report further noted that "the FDA suggested that [CytoDyn] file a second randomized protocol for all COVID-19 patients in severe condition, so as to preclude each physician from filing an emergency IND for every patient to be treated with leronlimab."

323. H.C. Wainwright issued another report on April 3, 2020 titled, "More Positive COVID-19 Clinical Results; Phase 2 Trials Initiated; Raising PT to $3." In the April 3, 2020 report,

under the headline, "**Leronlimab results in eight COVID-19 patients promising**," H.C. Wainwright stated, "Yesterday, CytoDyn announced that the three-day effect of leronlimab in eight severely ill COVID-19 patients (out of 10 patients enrolled under the emergency Investigational New Drug (IND) protocol) showed a significant improvement in immunologic biomarkers." (Emphasis in original). It further stated that "[t]he results were consistent with prior observations in the first four COVID-19 patients treated with leronlimab." H.C. Wainwright concluded, "In the wake of this update, we have added potential sales of leronlimab as COVID-19 therapy to our valuation," leading to an increase in "estimated market value" from $902 million to $1.7 billion, and increasing H.C. Wainwright's "12-month price target to $3 from $1.50 per share."

324. Defendants' statements set forth above in ¶¶ 312-21 collectively gave investors the misleading impression that: (i) they had information, results, or statistically significant data to support the "proof-of-concept" and mechanism of action of leronlimab with respect to COVID-19; (ii) the eIND results supported the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19; and (iii) the FDA had acted based on the eIND results to provide CytoDyn with the CD10 and CD12 trials, as well as additional eINDs. As set forth herein and in Section VIII.B, contemporaneous internal documentation clearly demonstrate that these statements were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. By electing to speak publicly about these issues and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts about these issues.

325. More specifically, Defendants' statements set forth above in ¶¶ 313, 315 and 317-21 that CytoDyn has "already shown data on four patients . . . that this [leronlimab] can be a therapy, especially in the severe cases" and "[a]ll eight [eIND patients] had immunological benefit," and that the "major," "spectacular," and "very strong" results of the eIND patients demonstrated, has, or "show[n]" "immunological benefit" and "demonstrated a significant improvement in several important immunological bio-markers," were materially false and

misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

326. Defendants' statements set forth above in ¶¶ 312, 314, and 316-17 concerning the FDA's role in CytoDyn's decision to design or conduct a Phase 3 trial for severe or critically ill COVID-19 patients or the FDA's purported view or consideration of or recommendations based upon, the eIND results or data were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] For example, Defendants' assertions that "due to" the eIND data "[t]he FDA . . . gave us Phase 2 green light" and "the FDA has worked with [CytoDyn] so quickly and able to expedite this since there was some positive [eIND] results" [redacted] *See* Section VIII.B. [redacted]

[redacted] As such, Defendants knew or were deliberately reckless in not knowing that, [redacted]

327. Defendants' statement set forth above in ¶ 317 that "we made those modifications" requested by the FDA to the CD10 protocol was materially false and misleading, omitted material facts, or lacked a reasonable basis when made because they knew or were deliberately reckless in not knowing that [redacted] Thus, Defendants knew or were deliberately reckless in not knowing that, [redacted]

328. On April 7, 2020, Pourhassan gave an interview to Fox Business. During the interview, Pourhassan stated:

> [T]he good thing about leronlimab is it had 840 patients use that in HIV with zero serious adverse event related to this product. . . . Now, when we went forward with the coronavirus, we were very surprised, pleasantly that the first two patients, one of them . . . self-extubated immediately within three days. The results that's coming out right now in the first 10 patients, as Dr. [Seethamraju] enrolled, ***we have seen very spectacular results*** and we are sending that to the FDA for the first seven patients that have gone seven days now. . . .

> ***Now we have seven day data that is really strong. So we're sending to FDA and asking for emergency approval, perhaps.***

329. On April 9, 2020, Defendants issued a press release titled, "Blood Samples at Day 0, 3 and 7 for Severely Ill COVID-19 Patients ***Clearly Indicate Leronlimab Has Significantly Reduced the Cytokine Storm in All (7) Patients*** and ***All Patients Demonstrated Immunological Benefit at Both Day 3 and Day 7***" (the "April 9, 2020 Press Release"). The April 9, 2020 Press Release quoted Dr. Patterson as stating, "***The Day-7 results from these patients demonstrates even more dramatic immune restoration***" and "[c]ollectively, ***these results are correlating with patients' recovery***."

330. Also on April 9, 2020, Pourhassan and Dr. Patterson answered questions as part of an interview conducted by Proactive Investors and paid for by CytoDyn. During the interview, with respect to the results from the initial eIND patients, Pourhassan stated, "[T]hese results are there is no joke here. Now, this is something that has been very, very carefully analyzed. ***These patients show immunological benefit. They show a cytokine storm reduction.*** . . . And we send the data, for that matter, to FDA this morning." In response to an inquiry about "the next steps . . . with all this great data" Pourhassan claimed that "Dr. Anthony Fauci, Sanjay Gupta, ***they all want data*** and they don't want to talk about how good we can do maybe."

331. On April 15, 2020, Pourhassan and Dr. Patterson answered questions as part of an interview conducted by Proactive Investors and paid for by CytoDyn. During the interview, Pourhassan stated, "I want to make sure everybody understand that ***the coronavirus effect that leronlimab has shown, it's not something that we made it up*** . . . . And now it looks like to me that ***this is the solution to coronavirus because of the results that we see*** . . . ." During the same interview, Dr. Patterson stated, "***we think that mechanism of action is playing out. We have the data to support that now***."

332. Market participants repeated and amplified Defendants' statements. For instance, H.C. Wainwright issued an April 7, 2020 report titled, "More Severely Ill COVID-19 Patients

Treated With Leronlimab; Reiterate Buy." The report concluded, "we do not preclude the possibility that the FDA may take regulator action to endorse leronlimab in view of potentially positive efficacy data from patients enrolled under the emergency IND alone." H.C. Wainwright issued another report on April 13, 2020 titled, "Leronlimab Helps More COVID-19 Patients Recover; Reiterate Buy." Under the headline, "**Leronlimab facilitates immunological restoration**," the report noted that "[t]he seven-day results demonstrate more dramatic immune restoration, according to management" and that "these results are correlated with recovery such that critically ill patients were removed from ventilators within seven days of treatment with leronlimab." (Emphasis in original). The report concluded: "In our view, the accumulating and consistent data showcase leronlimab's efficacy in helping COVID-19 patients . . . ."

333. Likewise, an April 9, 2020 article posted to *Seeking Alpha*, titled, "CytoDyn and COVID-19" noted that "CytoDyn has been on a tear as its potential to treat COVID-19 has captured investors' imaginations." The article further stated, "Now that CytoDyn's credentials in pursuit of COVID-19 have picked up traction, the share price is responding" noting that "since late March . . . the company's news flow is all about COVID-19; and the share price is responding positively," "COVID-19 has been a true godsend for CytoDyn['s] stock price," and Pourhassan "has effectively promoted the results to date." In an April 15, 2020 article posted to *Seeking Alpha*, titled, "CytoDyn: Understanding The COVID-19 Opportunity" the author reported that "Leronlimab continues to produce impressive reports about its remarkable ability to help mitigate the 'cytokine storm' and improve patient outcomes." The article stated, "blood samples from days 0, 3, and 7 established that Leronlimab encouraged substantial declines in the cytokine storm in all seven severely ill patients."

334. Defendants' statements set forth above in ¶¶ 328-31 collectively gave investors the misleading impression that (i) they had information, results, or statistically significant data to support the "proof-of-concept" and mechanism of action of leronlimab with respect to COVID-19; (ii) the eIND results supported the clinical efficacy and safety of leronlimab to treat COVID-

19 patients and/or an EUA for COVID-19; and (iii) the FDA had acted based on the eIND results to provide CytoDyn with the CD10 and CD12 trials, as well as additional eINDs. As set forth herein and in Section VIII.B, contemporaneous internal documentation clearly demonstrate that these statements were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. By electing to speak publicly about these issues and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts about these issues.

335. More specifically, Defendants' statements set forth above in ¶¶ 328-30 that the "spectacular" and "really strong" eIND results "[c]learly [i]ndicate[d] [l]eronlimab [h]as [s]ignificantly [r]educed the [c]ytokine [s]torm in [a]ll (7) [p]atients," "[a]ll [eIND] [p]atients [d]emonstrated [i]mmunological [b]enefit at [b]oth [d]ay 3 and [d]ay 7," "[t]he Day-7 results from th[e eIND] patients demonstrate[d] even more dramatic immune restoration," the eIND "results are correlating with patients' recovery," and "[t]hese [eIND] patients show immunological benefit" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted] Accordingly, Defendants knew or were deliberately reckless in not knowing that, [redacted]

336. For the same reasons, Defendants' statement set forth in ¶ 328 that CytoDyn was sending the "seven day [eIND] data" "to FDA and asking for emergency approval" was materially false and misleading, omitted material facts, or lacked a reasonable basis when made.

337. Additionally, Defendants' statements set forth in ¶ 331 above that the "mechanism of action is playing out" and "[w]e have the data to support that now" and that leronlimab "has shown" a "coronavirus effect" and "is the solution to coronavirus because of the [eIND] results that we see" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, [redacted] Accordingly, at the time Defendants told investors that they had the data to support the mechanism of action or proof-of-concept, they knew or were deliberately reckless in not knowing that [redacted]

338. Further, Defendants' statement set forth in the ¶ 330 above that "Dr. Anthony Fauci, Sanjay Gupta, they all want [the eIND] data" were materially false and misleading, omitted

material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, [redacted] And, as Defendants knew or were deliberately reckless in not knowing, [redacted]

339. On April 27, 2020, Pourhassan and Drs. Patterson and Lalezari participated in a conference call with investors. During the call, Dr. Patterson claimed on behalf of CytoDyn that "***treatment of leronlimab in [the eIND] patients brought IL-6 down by 14 days to normal levels***, which was truly amazing." He further asserted that "***leronlimab restored the immune cells***" of these patients "so that by day 14 the CD4/CD8 ratios . . . . were restored to normal over 14 days." He also claimed that "***leronlimab decreases plasma viral loads***," stating that it was "remarkable for one drug to restore the immune system, and decrease the viral burden in these patients."

340. During the same call, Dr. Lalezari claimed on behalf of CytoDyn that "[f]or the last two three weeks Nader and Bruce, and the core team and I have been sitting on ***these data that point to remarkable proof-of-concept***. . . ." According to Dr. Lalezari, "***[i]t's clear this drug is working. It's working better than we could have ever imagined***."

341. With respect to "compassionate use" of leronlimab to treat COVID-19, Dr. Lalezari stated on behalf of CytoDyn:

> On March 20th, we wrote the FDA suggesting that instead of an emergency IND process, we do a compassionate use [process], because it would be too much paperwork and too complicated, and ***that was based on seeing two of four patients at the Montefiore ICU be extubated within 48 hours -- which seem like a remarkable result --*** although, an anecdote

> at best -- but still, and at that point we said, let's do a compassionate use and not have these doctors who are so busy do all these [e]IND applications.
>
> We wrote them again on March 27th and said we would like to have a compassionate use protocol, ***because we now see*** that in four of four of these patients from the ICU that Dr. Patterson is ***showing us, this rapid balancing of the immune system*** -- CD4/CD8 counts, and rapid decreases in IL-6 and other cytokines. You know that's of course, it's a 1 and 16 chance that you get four wins in a row, but they said no.
>
> But then the key day was on April 8th, when we wrote back to them again and said the situation has become morally perilous in that we now see seven of seven patients having these incredible laboratory responses that Bruce is showing, and moreover, we now know that if they seem too good, they're not too good to be true because now we know that RANTES is driving the disease. . . .
>
> [T]his process is fundamentally being driven by RANTES and RANTES' job in life is to fundamentally bind to CCR5.
>
> So when we interrupt that access, we are breaking the basic parthenogenesis of the disease, and that explains these extraordinary laboratory findings, where seriously critically ill patients are showing return of immune homeostasis within days of a single SUB-Q injection. . . . then the last time we asked FDA for compassionate use, when Bruce remarkably showed the viral load decreases in all patients. . . . It's been fortunate in that it's all come through this hodgepodge of emergency IND. We are obviously trying to enroll the clinical studies as fast as we can. But in the meantime, there's no doubt in my mind anymore about how important a drug this is going to be for COVID-19.

342. During the same call, Dr. Patterson had the following colloquy with an investor on behalf of CytoDyn:

> [QUESTION:] So regarding the decreasing viral log, can you tell us how soon that happens, and what's the scale of decrease? And what's the duration of the viral load decrease? Does that suggest that the leronlimab could potentially be developed as a chronic therapy for COVID-19 vector patients?
>
> [PATTERSON:] The extent I can tell you is statistically significant, and it occurs within seven days. . . .

343. On April 30, 2020, Pourhassan participated in an interview conducted by Proactive Investors and paid for by CytoDyn. During the interview, Pourhassan stated:

> [T]his story is really, really amazing. We were not given even a green light from the FDA to go to phase two because rightfully we didn't have any animal studies. Dr. Harish Seethamraju from Montefiore Medical School from Albert Einstein College of Medicine, he's the one that injected two patient[s] and adamantly asked for emergency IND. When the first one of those two patients self extubated . . . ***that started to make the FDA feel more relaxed***, ***not only they give us a Phase 2 for mild-to-moderate patients, but we also got the severe patients, Phase 3.*** . . .

344. On May 1, 2020, Pourhassan and Dr. Patterson participated in a Wall Street Reporter's Next Super Stock livestream paid for by CytoDyn. During the livestream, Pourhassan participated in the following colloquy with the host of the conference, Jack Marks:

> [MARKS:] [W]hy is it so hard for the FDA to realize how many lives can be saved by using only leronlimab?
>
> * * *
>
> [POURHASSAN:] The FDA has the rules and regulations. They just don't get excited because somebody calls them to say, "hey, I got something to work on few people." They have well-established trials called placebo controlled clinical trials. . . . So please don't point fingers at 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 approval left and right and one after another.***

345. In response to a request to provide an "update status on . . . on 49 patients that have been treated with leronlimab" through eINDs during the same livestream, Pourhassan stated: "[W]hen we do emergency IND the FDA is in touch with the physician directly. . . . So ***I'm almost certain that they have, as they waived our waiting for pre-IND, then immediately put in Phase 2 because they saw the results.*** That's my guess."

346. During the same livestream, Dr. Patterson stated on behalf of CytoDyn:

> [W]e've been able to submit for publication . . . . ***statistically significant changes, associated with treatment with leronlimab*** that pre-date clinical trial, significant data. . . . "***[W]e know the mechanism"*** . . . . what's causing the death and the morbidity in covid and how is that drug affecting that and that ***we have statistical significance*** in the paper. So ***knowing that the mechanism is holding up and is clinically significant*** is giving us great confidence in both clinical trials ultimately being clinically significant. . . .

347. Dr. Patterson further stated on behalf of CytoDyn:

> 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 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.

348. On May 4, 2020, Defendants issued a press release titled, "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." With respect to compassionate use, it stated: "***CytoDyn has submitted a request to the FDA to grant expanded access, also known as 'compassionate use,'*** to make leronlimab available for patients not eligible" for the Company's CD10 and CD12 trials.

349. On May 6, 2020, Defendants issued a press release titled, "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." It stated the manuscript "describ[es] ***the immunological mechanism by which leronlimab restores immune function and impacts disease in COVID-19 patients***."

350. Also on May 6, 2020, Pourhassan participated in an interview conducted by Proactive Investors and paid for by CytoDyn. During the interview, Pourhassan stated: "***Dr. Patterson has a statistically significant data that*** means he took the blood of these patients and ***showed why leronlimab work.*** That should put a lot of doubters' minds at ease that, hey, ***the mechanism of action is clear***."

351. Market participants repeated and amplified Defendants' statements. For example, H.C. Wainwright issued a report on April 28, 2020, titled, "HIV Therapy Filing Completed; Leronlimab Decreases COVID-19 Viral Load; Reiterate Buy; Raising PT to $4," stating: "yesterday, management reported that leronlimab significantly decreases plasma viral load of COVID-19 within seven days of treatment" and "COVID-19 patients enrolled under the emergency Investigational New Drug (IND) protocol have already demonstrated dramatic immune restoration following only a single injection of leronlimab." H.C. Wainwright stated, "Leronlimab appear[ed] to be able to lower COVID-19 viral load as well as facilitate immunological restoration,

which is correlated with patients' extubation and recovery." The report concluded, "the accumulating data showcase leronlimab's efficacy in helping COVID-19 patients" and "in light of leronlimab's newly-discovered effectiveness in treating COVID-19," H.C. Wainwright increased its price target to $4. Additionally, an April 30, 2020 article posted to *Seeking Alpha*, titled, "CytoDyn: Managing My Position Following BLA Submission and COVID-19 Progress," stated that "[a]s other potential products start to falter, Leronlimab has continued to impress" and noting that "results from the first ten COVID-19 patients enrolled in eIND treatment . . . . showed that Leronlimab decreases plasma viral load and also restored immune cells."

352. H.C. Wainwright issued another report on May 7, 2020, titled, "Leronlimab Mechanism of Action in Treating COVID-19 Posted; Reiterate Buy." Under the headline, "**Leronlimab can restore immune homeostasis, decrease IL-6 and reduce SARS-CoV-2 viral load**," the report stated, "[t]hese data demonstrate a novel approach to address COVID-19 symptoms via disruption of the CCL5-CCR5 axis and support the rationale for randomized clinical studies of leronlimab in COVID-19." (Emphasis in original). The report concluded, "knowledge of the mechanism of action for leronlimab in COVID-19 helps us better understand how the application of leronlimab monotherapy has led to patients' extubation and recovery" and "[t]hus, we reiterate our Buy rating and $4 price target." A May 6, 2020 article posted to *Seeking Alpha*, titled, "CytoDyn's Answer To COVID-19" stated that "CytoDyn has notched a nice group of encouraging data from its COVID EIND patients" and "leronlimab has a tripartite MOA that knocks back COVID-19 more effectively than possible with a less comprehensive approach."

353. Defendants' statements set forth above in ¶¶ 339-50 collectively gave investors the misleading impression that (i) they had information, results, statistically significant data to support the "proof-of-concept" and mechanism of action of leronlimab with respect to COVID-19; (ii) the eIND results supported the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19; and (iii) the FDA had acted based on the eIND results to provide CytoDyn with the CD10 and CD12 trials, as well as additional eINDs. As set forth herein

and in Section VIII.B, contemporaneous internal documentation clearly demonstrate that these statements were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. By electing to speak publicly about these issues and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts about these issues.

354. More specifically, Defendants' statements set forth above in ¶¶ 339, 341-42, 346, and 349 that leronlimab "brought IL-6 down by 14 days to normal levels," "restored . . . cells," "decrease[d]" or "[r]educe[d] plasma viral loads," "rapid[ly] balanc[ed]" "the immune system," "restored" or "return[ed]" critically ill patients to "immune homeostasis," "[d]isrupt[ed] CCL5/RANTES-CCR5 [p]athway" and "[r]everse[d] [h]yper [i]mmune [a]ctivation and [i]nflammation in [c]ritical COVID-19 [p]atients," as well as statements claiming that the decrease in COVID-19 viral load due to leronlimab was "statistically significant" and occurred within seven days" and CytoDyn was "submit[ting] for publication . . . . statistically significant changes associated with treatment with leronlimab" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. This is because Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted] Accordingly, Defendants knew or were deliberately reckless in not knowing that, [redacted]

355. Defendants' statements set forth above in ¶¶ 340, 346-47 and 350 that the eIND data "point to remarkable proof-of-concept," "we know the mechanism," "the mechanism is holding up and is clinically significant," and "the mechanism of action is clear," and that "[i]t's clear this drug is working" and "is doing what it's supposed to be doing" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made for the same reasons as are set forth above in ¶¶ 334-37 and 353-54.

356. Defendants' statements set forth above in ¶¶ 339-50 regarding the FDA's purported view or consideration of, or decisions based upon, the eIND results or data were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] For example, Defendants' assertions that the eIND data "started to make the FDA feel more relaxed" such that CytoDyn got "a Phase 2 for mild-to-moderate [COVID-19] patients" and "the severe patients, Phase 3," and "[o]bviously, they [the FDA] believe that we have something here" and "that's why they've been giving us Phase 2 and Phase 3 and [e]IND approval," [redacted]

[redacted] As such, Defendants knew or were deliberately reckless in not knowing that, [redacted]

357. Likewise, Defendants' statements set forth above in ¶¶ 341 and 348 concerning CytoDyn's March 20, March 27, April 8, and May 4, 2020 requests for a compassionate use protocol based on the eIND results were materially false and misleading, omitted material facts, or lacked a reasonable basis when made for the same reasons and because Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted] Thus, Defendants' statements concerning CytoDyn's March 20, March 27, April 8, and May 4, 2020 requests for approval of a compassionate use protocol were materially false or misleading, omitted material facts, or lacked a reasonable basis when made because Defendants failed to disclose that [redacted]

358. On June 2, 2020, Pourhassan and Dr. Lalezari participated in a Wall Street Reporter Next Super Stock livestream. During the livestream, Pourhassan stated:

> But as of last night or yesterday afternoon, [the] FDA send us an urgent letter that we are not going to give CytoDyn any more emergency IND to do in the hospitals. And their reasoning was absolutely right on. They're saying that "We need you to finish the trial." Just like the shareholders that we have can't wait for us to complete if they also want us to focus on finishing and completing the trials. The trial is sometimes difficult to enroll. ***But what we have heard from FDA in the letter is*** if you are able to see that patients need emergency IND, and if you took this much time to enroll and have 60 patients in the emergency IND[s] so therefore you must focus on finishing your trial. ***And if you believe you have something that works, let's give it to thousands and thousands and thousands, not just 70 patients.*** . . . And I'm very happy to see that FDA is also looking at our manufacturing, the production capability, and all of those things, which means very, very positive for us.

359. During the same livestream, Dr. Lalezari stated on behalf of CytoDyn:

> [I]t is unique to have so many patients treated under emergency IND[s], such that we knew the drug was working before we knew how and we knew the drug was working before we've been able to even enroll our clinical studies. There's no precedent for this in the history of drug development with the FDA.

360. Dr. Lalezari also engaged in the following colloquy with another investor on behalf of CytoDyn:

> [QUESTION:] [W]hat data exists that shows that these points improve, that these patients improved as a result of leronlimab not just as a spontaneous resolution of the virus?

* * *

> [LALEZARI:] You know, that's really one of the sticking points in all of this. When people look at the amount of your data and they say, "well, too bad it didn't correlate with clinical outcome." It's not like we took snapshots of patients who are all getting better . . . . These were patients who mostly were renal transplant on dialysis, intubated, very sick and very terminal. ***So we got . . . stunning 100% response rate in terms of the immune system and CytoDyn.*** . . . If you look at the and eIND the data set, like from UCLA, you see that ***there's a clear trend that patients who are dosed, whether they're mild-to-severe or they're critical, that they start improving over that same two to three day time frame.*** So obviously, we need randomized placebo controlled studies to demonstrate clinical proof of concept. 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 eIND results evidence of the same clinical benefit.***

361. 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 on behalf of CytoDyn:

> I'm not sure I want to speculate too much on the future, but 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. And leronlimab isn't even an antiviral. That antiviral effect is the result of immune system restoring balance. CD8 [coming] up and IL-6 coming down. And it's all happening over a 48 to 72 hour period. So, yes, ***it is utterly amazing how well and that effect is being seen in 100% 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] drug would work from emergency IND data before we even understood how it was working or even before you had randomized clinical studies.***

362. 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:

> So we got . . . stunning 100% response rate in terms of the immune system and CytoDyn. . . . 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.

363. On June 15, 2020, Pourhassan participated in an interview conducted by Proactive Investors and paid for by CytoDyn. During the interview, Pourhassan stated:

> As our scientists explain, cytokine storm has many components. We are the only company, we believe, that takes care of all those components, not just one or two . . . . So it's very exciting to see a product like this showing the results in emergency IND [in] over 70 patient. No company has 70 patients emergency IND . . . nobody in the world. So these are very exciting time for us.

364. During the same interview, Pourhassan further stated: "FDA has been extremely positive with us and helping us and guiding us. They had us stop the emergency IND to make sure that we focus on the enrollment."

365. On July 4, 2020, Pourhassan participated in a discussion with Dr. Been. During the discussion, Pourhassan stated:

> [W]hen . . . Dr. Scott Kelly told me that, you know, it's not the virus [COVID-19], it's . . . what the virus does to the body which causes it to have ARDS, and we have an impact on that. . . So we . . . called our regulatory team and said — immediately file IND (Initial New Drug Application) and a protocol for Phase 2. . . .
>
> When we did that, FDA says "hold on . . . we're not going to give you Phase 2 for COVID-19 [be]cause you don't have any animal study group. You don't even have an in vitro study. Give us something to help you."
>
> So 60 days waiting and then another 30 days, so it'd be 3 months and maybe more waiting. That's when Dr. Seethamraju from Montefiore . . . . gave [leronlimab] to . . . the first two patients . . . . And ***that's started everything, and then the whole thing that we have right now, as you can see where we are***.
>
> * * *
>
> Dr. Seethamraju asked for nine more emergency IND immediately. . . . eleven patients were given the drug. Some of them start dying, not because of leronlimab, because they stopped giving them treatment of ventilation, they were — those conditions were gotten because the resources are limited.
>
> But then . . . four patients actually live, and a lot of, the other ones were not dying . . . .
>
> Twenty nine patients got injected at [UCLA]. Many of them were discharged, many of them got intubated. . . .
>
> So all of this led us that – hey, we need to have FDA give us Phase 2, but already FDA, as soon as they saw what happened with Dr. Seethamraju's patient, immediately FDA worked with us. They did not delay it a day. They said – you got Phase 2, go forward.

(Some emphasis in original).

366. On October 20, 2020, Defendants held a conference call for investors. During the call, Pourhassan stated: "Over 60 emergency IND applications were approved by the FDA for CytoDyn, ***which opened the door for us to have a chance to do a randomized Phase 3 in this***

severe to critical population." Pourhassan further confirmed that the "***FDA looked at [the emergency IND data] and allowed us to skip six weeks or so to give us Phase 3.***"

367. Pourhassan further claimed on a November 5, 2020 conference call that data from eIND patients at Montefiore and UCLA, among others, "***led us to be able to initiate a Phase 2 and a Phase 3 that had green light from FDA to begin***."

368. Market participants repeated and amplified Defendants' statements. For example, a June 4, 2020 article posted to *Seeking Alpha*, titled, "CytoDyn: COVID-19 Crunch Time" noted, "[a]ll told CytoDyn's EIND program has to be counted as a resounding success. Not only did it give the stock a much-needed boost, it generated a favorable NEJM article from the Montefiore doctors."

369. Defendants' statements set forth above in ¶¶ 358-67 collectively gave investors the misleading impression that (i) they had information, results, or statistically significant data to support the "proof-of-concept" and mechanism of action of leronlimab with respect to COVID-19; (ii) the eIND results supported the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19; and (iii) the FDA had acted based on the eIND results to provide CytoDyn with the CD10 and CD12 trials, as well as additional eINDs. As set forth herein and in Section VIII.B, contemporaneous internal documentation clearly demonstrate that these statements were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. By electing to speak publicly about these issues and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts about these issues.

370. More specifically, Defendants' statements set forth above in ¶¶ 358 and 364 regarding the FDA's June 1, 2020 decision to stop authorizing eINDs were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted] Because Defendants chose to tell investors about the FDA's June 1, 2020 correspondence, and specifically why the FDA had stopped authorizing the eINDs, their statements charactering the FDA's June 1, 2020 decision to stop eINDs was materially false and misleading when made because Defendants failed to disclose all material information about the FDA's decision to investors.

371. Defendants' statements set forth above in ¶¶ 358-67 regarding the FDA's purported view or consideration of, or decisions based upon the eIND results or data were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] For example, Defendants' assertions that "as soon as they saw what happened with" the eIND patients the "FDA worked with us" and "said – you got Phase 2, go forward," "FDA looked at [the emergency IND data] and allowed us to skip six weeks or so to give us Phase 3," the eIND data "led us to be able to initiate a Phase 2 and a Phase 3," [redacted] *See* Section VIII.B. [redacted]

[redacted] Accordingly, Defendants knew or were deliberately reckless in not knowing that, [redacted]

372. Defendants' statements set forth above in ¶¶ 340 and 359-61 that they knew "the drug was working" "from emergency IND data," and they "see" "evidence of . . . clinical benefit" in the "[e]IND results" as well as "stunning 100% response rate" in eIND patients' immune systems and leronlimab's "effect . . . in 100% of [eIND] patients," with these patients "start[ing to] improve[]" in a "two to three day time frame" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made for the same reasons as are set forth above in ¶¶ 357 and 370. [redacted]

373. These statements also 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 [redacted]

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

374. On July 30, 2020, Defendants held a conference call with investors. During the call, Pourhassan stated:

> First and most important update is our COVID-19 trials. CD-10 study is for mild-to-moderate population. This population is the toughest population to show improvement with any drug. . . .
>
> This is due to most of these patients recover, if not in 4 to 7 days, but for sure 14 days. And to the best of our knowledge, no one has ever received any positive efficacy results better than placebo in this population in a randomized double-blinded FDA trials. . . .
>
> * * *
>
> [A]s of today, ***we do have positive efficacy results in [C]D10*** and the data is still being evaluated to find more positive aspects. In regards to our primary endpoint, clinical improvement was scored in four categories: fever, body aches, difficulty to breathe, and cough. ***We have seen improvement in day t3 versus day zero in leronlimab arm as compared to placebo arm. . . .***
>
> ***So that is the first major positive result for us***. ***A very important secondary endpoint is called N.E.W.S. 2***, which is a upgraded version of N.E.W.S. stands for National Early Warning Score. N.E.W.S. 2 assesses the degree of illness that points out to any need for critical care interventions. . . .
>
> Very, very crucial parameter. . . .
>
> In regards to the very crucial parameters, we have seen good improvements in leronlimab arm compared to placebo arm in all evaluated days. Which is day three, day seven, and day 14. We are so delighted with this results. . . .
>
> We hope to have the top line report within 10 days or so.

(Some emphasis in original).

375. On August 5, 2020, Pourhassan and Dr. Lalezari participated in an interview conducted by Proactive Investors and paid for by CytoDyn. During the interview, Pourhassan stated:

> In the CD10, we announced that we found parameters. Now, the Phase 2 is a proof-of-concept. Any parameter in your secondary outcome or primary outcome is just perfect, if you can find a perfect difference between leronlimab and placebo. ***We found them, and we're going to — and I told everybody — we believe it's statistically significant, and we're going to give the p-value,*** and we have to finalize those reports before we can give exact [numbers].

376. Pourhassan also stated:

> Now, what does that parameter mean? That means now you go back to the FDA, you can do Phase 3, but if you're in pandemic and say — the FDA recognizes that what you found was good enough to go to approval and do, perhaps, Phase 4. That could happen — that's CD10, mild-to-moderate.

377. On August 11, 2020, Defendants issued a press release titled, "CytoDyn Announces Clinically Significant Top-line Results from its Phase 2 Trial in Mild-to-Moderate COVID-19 Patients." According to the press release, leronlimab "***demonstrated statistically significant improvement versus placebo in key secondary efficacy endpoint, National Early Warning Score 2 scale (NEWS2).***" (Some emphasis in original). The press release further stated, "***statistically significant[] results were observed at Day 3 and Day 14***" in the NEWS2 scores "***in the analysis of per protocol population (p<0.03 and p<0.02, respectively).***"

378. The August 11, 2020 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 . . . [I]n the U.S." The press release also quoted Kelly as follows: "We are pleased that ***leronlimab showed a statistically significant result in a randomized, double-blinded study for NEWS2.***"

379. On August 12, 2020, Defendants held a conference call with investors. During the call, Pourhassan stated, "As of about an hour ago, ***CytoDyn has requested from the FDA to grant***

CytoDyn an Emergency Use Authorization for Leronlimab based on CD10 data for mild to moderate COVID-19 population."

380. During the same call, Pourhassan also stated:

> [B]ut something happened to this trial, something fantastic we have discovered. We discovered that the secondary endpoint, that we believe is even more important than our primary endpoint, and ***we have achieved a statistically significance value which is the so-called NEWS2***, which is optic vision of NEWS. N-E-W-S, which is National Early Warning Score. NEWS2 assesses the degree of illness that points out to any need for critical care intervention. This means we've lowered this risk of having this combination of 7 parameters that constitute the NEWS score, and we have done it by 250 percent better than the placebo.

381. Additionally, Kelly stated, "The National Early Warning Score or NEWS2 provides objective evidence of clinical deterioration. . . . ***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. I think that's remarkable."

382. Dr. Lalezari likewise stated on behalf of CytoDyn: "[T]he results of CD10 lay to rest the question of whether Leronlimab works at all in COVID-19. It unquestionably does, based on clinical outcomes . . . . So, the drug works . . . . I think we have our first drug that actually works on COVID-19."

383. In response to an analyst query, Dr. Lalezari stated on behalf of CytoDyn, the day 3 "results are great, and they certainly comport with what we reported from the emergency IND patients. So, ***what that's telling is that the mechanism and the activity that we thought we had is there.*** But in terms of importance . . . the NEWS2 endpoint . . . that is ultimately what is most important." Further, Kelly "agree[d] with" Dr. Lalezari's statement, "due to the objectivity of the NEWS2 versus the subjectivity of the symptom scale."

384. During the same call, in response to a question regarding non-clinical data, Pourhassan stated with respect to CD10, "[b]ut we have seen what we got from the clinical outcome ***which is their protocol,*** and those are the one that we are submitting" in the CD10 topline report. Kelly agreed with Pourhassan's statement, "I think that's exactly correct."

385. 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 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.

386. In an August 17, 2020 paid for interview with Proactive Investors, Pourhassan further stated:

> Now, there are two outcomes. Worst case, best case. Best case is the FDA will come back and say, you know, the EUA, emergency use[] authorization is granted. We hope to hear about that, whether yes or no this week or so. The second case is when you have a successful Phase 2 with a statistically significant endpoint and a clinically significant primary endpoint, that you do a Phase 3 perhaps. Well, worst case scenario, we do a Phase 3. The population would be 100 patients still. And we know we had NEWS2 parameter or endpoint very well. So we will repeat it and hopefully have approval by the end of the year. That's what we believe.

(Brackets in original).

387. 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 Notable Safety Results," where Pourhassan again touted the Phase 2 Trial (CD10) "***statistically significant efficacy findings***." Pourhassan further claimed that the CD10 results were "***significant***" and "***show efficacy***."

388. 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 Pourhassan likewise touted the Phase 2 Trial (CD10) as having "***strong efficacy . . . data***." In a same-day paid for interview with Proactive Investors, Pourhassan further stated:

> So the Phase 2, as we said . . . . we saw that very powerful situation here with NEWS2, which is much better endpoint for us. And ***we had that statistically significant.*** So to redo a trial and making that the primary endpoint would be very quick for us either way. ***So best case scenario, approval very soon. Worst case scenario approval by the end of the year is what we are guessing.***

389. On September 2, 2020, Defendants held a conference call with investors. During the call, Dr. Lalezari stated:

> I think when you look at CD10 and it is impossible to conclude anything other than the drug works.
>
> In terms of the primary endpoint, having 90% versus 70% of patients improved their total clinical score at day 3, in a study where about half the patients were at home with no symptoms at all is a remarkable result. And when you add in ***the statistically significant impact on these two outcomes*** and the reduction of SAEs unheard of by over 50%. ***I think it's impossible to conclude [] anything other than the drug is working*** and that there are folks who are promoting the idea that it's not working, but they're working off a different agenda.

390. During the same call, in response to a question regarding a "p-value" for the serious adverse events in CD10, Pourhassan stated, "they don't do p-value on SAEs" but the increase of SAEs in the placebo arm "tells me . . . and the other doctors who I talked to, that ***leronlimab is correcting the immune system*** . . . ." In response to the same question, Kelly stated, "when you think about COVID-19 as a multi-system inflammatory disorder, we think that the reason that you're having less serious adverse events and adverse events is due to the effects of leronlimab in this population. And the fact . . . that COVID is actually causing this problem and that ***leronlimab we believe is helping to correct that problem***."

391. Market participants repeated and amplified Defendants' statements. For example, on August 17, 2020, H.C. Wainwright issued a report titled, "FY2020 Financial Results; Positive Phase 2 Data in COVID-19; Reiterate Neutral." Under the headline, "**Statistically significant data seen in mild-to-moderate COVID-19**," the report stated that "in all treated patients, patients in the leronlimab group were more than twice as likely to experience a beneficial improvement in the National Early Warning Score 2 (NEWS2) compared to patients in the placebo group (50% vs 20%; p=0.0223) at the end of treatment (Day14)." (Emphasis in original). The report also noted,

"Statistically significant results were also observed at Day 3 and Day 14 in the analyses of per protocol population ($p<0.03$ and $p<0.02$, respectively)." The report concluded, "These results show that leronlimab . . . in mild-to-moderate COVID-19 patients is safe and can deliver rapid improvement in symptoms associated with the coronavirus infection."

392. An August 26, 2020 article posted to *Seeking Alpha*, titled, "CytoDyn In Treatment Of COVID-19: The BP Saga," provided the key points from the August 12, 2020 conference call including, the "Company has applied for emergency use of the drug to treat [mild-to-moderate COVID-19] patients in the U.S." and "the NEWS2 secondary endpoint . . . was met."

393. Defendants' statements set forth above in ¶¶ 374-90 collectively gave investors the misleading impression that (i) they had information, results, or statistically significant data to support the "proof-of-concept" and mechanism of action of leronlimab with respect to COVID-19; (ii) the CD10 results and/or data supported the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19, and, in particular, that CytoDyn met the NEWS2 secondary endpoint utilizing per protocol or pre-specified analyses; and (iii) Defendants had requested—and it was possible for the FDA to grant—EUA for mild-to-moderate COVID-19 patients based on the CD10 results and/or data. As set forth herein and in Section VIII.B, contemporaneous internal documentation clearly demonstrate that these statements were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. By electing to speak publicly about these issues and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts about these issues.

394. More specifically, Defendants' statements set forth above in ¶¶ 377-78 and 380-81 that, with respect to the NEWS2 secondary endpoint, they have "observed" "statistically significant results," "showed statistical significance," and "achieved a statistically significant value," and that "[p]atients . . . showed a statistically significant improvement," and "[l]eronlimab showed a statistically significant result" were materially false and misleading, omitted material

facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that: [redacted] As such, Defendants' failure to disclose that CD10 had not, in fact, met the NEWS2 secondary endpoint [redacted] left investors with the misleading impression that CD10 had met one of its endpoints and the NEWS2 results could support or otherwise establish effectiveness of leronlimab in mild-to-moderate COVID-19 patients, when in reality the results could not support an EUA or other approval of COVID-19 for mild-to-moderate illness.

395. Likewise, Defendants' statements set forth above in ¶¶ 374-75, 382, and 387-88 that with respect to CD10, they "have positive efficacy results" and "found" a "statistically significant" "difference between leronlimab and placebo," and have ""statistically significant efficacy findings," that the CD10 results were "significant," "show[ed] efficacy," and included

"strong efficacy . . . data," and that the CD10 "clinical outcomes" were "per protocol" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made for the same reasons.

396. Additionally, Defendants' statements set forth above in ¶¶ 382 and 389-90 that based on the CD10 results leronlimab "unquestionably" "works . . . in COVID-19" and "it is impossible to conclude anything other than the drug works" or "is working," "leronlimab is correcting the immune system" and "correct[ing] th[e] problem," "that the mechanism and the activity that we thought we had is there," and that leronlimab is the "first drug that actually works in COVID-19" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that that, [redacted] Accordingly, at the time Defendants told investors that they had the data or results to support the mechanism of action or proof-of-concept, let alone "clinical benefit," they knew or were deliberately reckless in not knowing that [redacted]

397. Defendants' statements set forth above in ¶¶ 376 and 379 that FDA "approval" "could happen" in "mild-to-moderate" with CD10, and "CytoDyn ha[d] requested from the FDA to grant CytoDyn an Emergency Use Authorization for Leronlimab based on CD10 data for mild to moderate COVID-19 population" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, [redacted] Thus, Defendants knew or were deliberately reckless in not knowing that, contrary to their statements, they had not actually "requested" an EUA for mild-to-moderate COVID-19 patients but rather had sought the FDA's opinion [redacted]

398. On September 23, 2020, Pourhassan and Kelly participated in a discussion with Dr. Been. During the discussion, Pourhassan stated:

> We did a study mild-to-moderate. It was a Phase 2 study, and it was 84, 86 patients (84 available). And the results came out, and we said — ***we had a fantastic results***, in our opinion. . . .
>
> * * *
>
> ***[W]e have hit two endpoints***, and we've got a top line report. . . .

> That result also gave us total understanding of our product in some COVID-19 patients, and that's very valuable, very huge result for us. We 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.

399. Pourhassan also stated:

> ***So we found, in the Phase 2, what we can be effective in, for the mild-to-moderate population***. That's what Phase 2 is for: investigate your products, see if you have any kind of endpoint.
>
> Now 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. The CD10 obviously was very fantastic.

400. On October 9, 2020, CytoDyn filed its 1Q21 Form 10-Q. Signed and certified by Pourhassan and Mulholland, the 1Q21 Form 10-Q stated, "The topline report from the [CD10] trial, including efficacy and complete safety data ***demonstrated . . . statistically significant results for the secondary outcome for NEWS2***, was submitted to the FDA in August 2020."

401. On January 6, 2021, Defendants held a conference call with investors. During the call, Pourhassan stated that with respect to CD10, ***"[t]he secondary endpoint that was positive for us to go forward with Phase 3[,] was great for us***, we could go to Phase 3 with moderate perhaps or others. ***But we decided instead of going and trying to meet with the FDA and do a Phase 3 on the information that we have learned, which was very valuable to us, we will concentrate all of our effort on CD12***."

402. Analysts reiterated and amplified Defendants' statements. For instance, H.C. Wainwright issued a report on September 18, 2020, titled, "Emergency Approval for COVID-19 Requires Additional Data; Reiterate Neutral." The report noted, "the company has previously reported positive top-line results from the Phase 2 trial (CD10) of leronlimab in mild-to-moderate COVID-19 patients" and "the company plans to initiate a Phase 3 trial of leronlimab in mild-to-moderate COVID-19 patients." The report concluded, "[w]e believe that the FDA's decision [not to grant EUA] is based on the fact that severe and critical COVID-19 patients constitute those who

need effective and safe medicines the most at this time." H.C. Wainwright repeated similar statements in an October 21, 2020 report titled, "COVID-19 Trial Slated to Continue After Interim Analysis; Reiterate Neutral."

403. Defendants' statements set forth above in ¶¶ 398-401 collectively gave investors the misleading impression that (i) they had information, results, or statistically significant data to support the "proof-of-concept" and mechanism of action of leronlimab with respect to COVID-19; (ii) the CD10 results and/or data supported the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19, and, in particular, that CytoDyn met the NEWS2 secondary endpoint utilizing per protocol or pre-specified analyses; and (iii) Defendants had requested—and it was possible for the FDA to grant—EUA for mild-to-moderate COVID-19 patients based on the CD10 results and/or data. As set forth herein and in Section VIII.B, contemporaneous internal documentation clearly demonstrate that these statements were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. By electing to speak publicly about these issues and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts about these issues.

404. In particular, Defendants' statements set forth above in ¶ 400 that the CD10 trial "demonstrated . . . statistically significant results for . . . NEWS2," and "we did have a statistically significant NEWS value for day 14" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made for the same reasons as are set forth above in ¶¶ 393-94.

405. Defendants' claims concerning a Phase 3 trial in mild-to-moderate COVID-19 patients set forth in ¶¶ 398-99 and 401 above, including that they were "going with Phase 3" for mild-to-moderate COVID-19 patients, that when they "asked [the] FDA" about the Phase 3 trial, the "FDA said, 'let's talk,'" that "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," that NEWS2 "was positive for us to go forward with Phase 3," were materially

false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] Therefore, Defendants knew or were deliberately reckless in not knowing that, [redacted]

406. On January 8, 2021, CytoDyn filed its 2Q21 Form 10-Q. Signed and certified by Pourhassan and Mulholland, the 2Q21 Form 10-Q stated, "The topline report from the [CD10] trial, including efficacy and complete safety data, ***demonstrated . . . statistically significant results for the secondary outcome for NEWS2*** was submitted to the FDA in August 2020."

407. On April 14, 2021, CytoDyn filed its 3Q21 Form 10-Q. Signed and certified by Pourhassan and Mulholland, the 3Q21 Form 10-Q stated, "The topline report from the [CD10] trial, including efficacy and complete safety data, ***demonstrated . . . statistically significant results for the secondary outcome for NEWS2*** was submitted to the FDA in August 2020.

408. Defendants' statements set forth above in ¶¶ 406-407 collectively gave investors the misleading impression that (i) Defendants had information, results, or statistically significant data to support the "proof-of-concept" and mechanism of action of leronlimab with respect to COVID-19; (ii) the CD10 results and/or data supported the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19, and, in particular, that CytoDyn met the NEWS2 secondary endpoint utilizing per protocol or pre-specified analyses; and (iii) Defendants had requested—and it was possible for the FDA to grant—EUA for mild-to-moderate COVID-19 patients based on the CD10 results and/or data. As set forth herein and in

Section VIII.B, contemporaneous internal documentation clearly demonstrate that the statements set forth in ¶¶ 406-407 were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. By electing to speak publicly about these issues and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts about these issues.

409. In particular, Defendants' statements set forth above in ¶¶ 406-407 that the CD10 trial "demonstrated . . . statistically significant results for the secondary outcome NEWS2" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made for the same reasons as are set forth above in ¶ 408.

410. Moreover, [redacted] Defendants knew or were deliberately reckless in disregarding that [redacted]

411. [redacted]

3. Statements Concerning the Phase 2b/3 Trial (CD12) Results

412. 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"). It stated, the "[h]ighlights from the trial's data for this critically ill population" included "[s]hortened time to recovery: The 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."

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

> ***Our 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 . . . The Company is . . . ***concurrently working with regulators here and abroad to expedite leronlimab's approval to treat COVID-19***.

414. 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***."

415. 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.

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

417. 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." It included the statements set forth above in ¶¶ 412 and 415. Additionally, it stated, "[a]fter communications with MHRA, Health Canada, and U.S. FDA, CytoDyn has its path to approval by conducting another study of 140 patients in the critically ill population with the same sites as the CD12 [trial] and/or more sites added."

418. Additionally, on March 8, 2021, Defendants held a conference call with investors. During the call, Pourhassan stated:

> On April 15, 2020, less than a year ago, just one year ago, we injected the first patient in CD12. On Friday, we announced not only very strong results of 394 patient trial, but the fact that three regulatory agency including U.S. FDA are working with us and have suggested the final path to approval of leronlimab for COVID-19 in multiple countries including USA. . . .
>
> [W]e believe CD12 demonstrated that leronlimab works as an immunomodulator which means we believe leronlimab helps regulate one's own immune system to fight disease. In our opinion, this was proven in CD12, which showed statistically significant secondary

> endpoint and it showed superiority to many of the other drugs in use to fight and specially difficult disease like COVID-19 . . . .
>
> We are very grateful to the U.S. FDA allowing us to extend CD12 trial to generate more data to demonstrate we can achieve statistically significant p-value and not only get EUA, but also file a BLA for full approval.

419. Speaking for CytoDyn, Dr. 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." Dr. Rahman continued, "Then if you look at the ***time to recovery or discharge from hospitals, our hospital stay in this [critically ill] patient population, you actually see a statistically significant difference, 6 days less in this patient population***.

420. Dr. Rahman also stated, "[a]nd in one of the endpoints, the hospital stay, we actually got statistically significant results" in the critically ill population.

421. Additionally, during the same call Pourhassan stated, "[w]e met with the regulatory agencies and ***we have a path to go forward to get final approval***." Pourhassan likewise stated, "I think everybody would agree that when FDA says do another trial to show that the critical population is solid, your data, ***that means they're seeing a signal and they're seeing a need*** that perhaps they can work with us."

422. 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"). Mulholland signed the March 8, 2021 Form 8-K.

423. With respect to the leronlimab + SoC and leronlimab + dexamethasone subgroups, 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**.

(Emphases in original.)

424. With respect to members of the critically-ill population subgroup, the March 8, 2021 Form 8-K stated: "**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." (Emphasis in original).

425. Moreover, the March 8, 2021 Form 8-K identified a "***relative reduction***" in risk for a number of subgroup populations, including a "relative reduction" in mortality (CD10's primary endpoint) for patients ≤ 65y, leronlimab + SoC, leronlimab + dexamethasone, and critically ill patients, and in combinations of these subgroup populations, including a "relative reduction" in mortality for patients ≤ 65y receiving leronlimab + SoC or leronlimab + dexamethasone, and critical patients ≤ 65y receiving leronlimab + SoC or leronlimab + dexamethasone.

426. Market participants repeated and emphasized Defendants' statements. For example, in a March 12, 2021 article posted to *Seeking Alpha*, titled, "CytoDyn: Preparing For Capitulation After A Successful Failure," the author noted that "[a]fter some analysis, the company revealed a subset of patients who benefited from Leronlimab." Describing these results as "encouraging," the article reflected "optimis[m] about Leronlimab's chances of moving forward in COVID-19." The article stated, "[d]espite the shortcomings, the CD12 trial results do support Leronlimab's potential to be the only safe medication to help some critically ill COVID-19 patients" and noted, "the data actually makes sense for what Leronlimab is capable of doing and when Leronlimab can have an impact on COVID-19."

427. Similarly, a March 17, 2021 article posted to *Seeking Alpha* titled, "A New Look At CytoDyn's Severe-To-Critical COVID-19 Trial" noted that the CD12 "[t]rial data is supportive of an EUA" because "Leronlimab outperformed every approved or recommended drug in critically

ill patients." The article concluded, "[i]t is fairly clear, given the congruency of the leronlimab CD12 trial data and the magnitude of the therapeutic benefit seen therein, that *leronlimab works*" and "[t]his closer look at the data shows that leronlimab most likely will be approved or issued a conditional Emergency Use Authorization (EUA) sometime soon." (Emphasis in original).

428. Defendants' statements set forth above in ¶¶ 418-25 collectively gave investors the misleading impression that (i) they had information, results, or statistically significant data to support the proof-of-concept or mechanism of action of leronlimab with respect to COVID-19; (ii) the CD12 results and/or data supported the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19; (iii) the statistically significant results in CD12's primary and secondary endpoints for the critically ill subgroup population and the related relative reduction of the risk of mortality were sufficient to support an EUA and/or additional clinical trials in the U.S.; and (iv) the CD12 extension would generate data that could support the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19. As set forth herein and in Section VIII.B, contemporaneous internal documentation clearly demonstrate that these statements were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. By electing to speak publicly about these issues and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts.

429. More specifically, Defendants' statement set forth above in ¶ 418 that CD12 "showed [a] statistically significant secondary endpoint" was materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

430. Defendants' statements set forth above in ¶¶ 413-14, 419, and 425 that, with respect to the critically ill population subgroup, CD12 "demonstrate[d] leronlimab is particularly effective in treating" this population, "show[ed] strong data for" these patients, and demonstrated "a

statistically significant difference" or p-value in "time to recovery or discharge from hospital," a "relative reduction" in mortality, and a "consistent[]" "benefit" "in essentially all different endpoints" in this population subgroup were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that, [redacted]

431. Defendants also knew or were deliberately reckless in not knowing that [redacted]

[redacted]

[redacted]

432. Accordingly, Defendants knew or were deliberately reckless in not knowing that, contrary to their assertions about CD12's purportedly statistically significant results in the critically ill population subgroup, [redacted]

[redacted]

[redacted]

433. Additionally, Defendants' statements set forth above in ¶¶ 412-15 and 422-25 identifying "statistically significant results" for the primary endpoint for two subgroups, leronlimab + SoC and leronlimab + dexamethasone, as well as a relative reduction of risk of mortality in a number of subgroup populations were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted]

434. Defendants' statements set forth above in ¶ 418 that "CD12 demonstrated that leronlimab works as an immunomodulator" and "showed" that leronlimab was "superior[] to many of the other drugs" in treating COVID-19 were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

435. Defendants' statements set forth above in ¶¶ 413-14, 418, and 421 that CytoDyn was "concurrently working with regulators here and aboard to expedite leronlimab's approval to treat COVID-19," had "multiple regulatory pathways for approval of leronlimab as a treatment for critical COVID-19 patients in the U.S.," "3 regulatory agenc[ies], including U.S. FDA, are working with us and have suggested the final path to approval for COVID-19 in multiple countries,

including USA," and "we met with the regulatory agencies and we have a path to go forward to get final approval" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] Similarly, Defendants knew or were deliberately reckless in not knowing that [redacted] As such, Defendants knew or were deliberately reckless in not knowing that, contrary to their statements regarding multiple pathways to approval based on the CD12 results, [redacted]

436. Defendants' statement set forth above in ¶ 418 that the "U.S. FDA allow[ed] us to extend CD12 trial to generate more data to demonstrate we can achieve statistically significant p-value and not only get EUA but also file a BLA for full approval" was materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] As an initial matter, Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted]

437. Moreover, [redacted] Accordingly, Defendants' statements concerning the use of the CD12 open label extension trial data to support an EUA were materially false and misleading, omitted material information, or lacked a reasonable basis when made.

438. Defendants' statements set forth above in ¶ 421 that the FDA told them to "do another trial" in the critically ill COVID-19 population and "that means they're [the FDA] seeing a signal" in the CD12 data and "they're seeing a need" were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. That is because Defendants knew or were deliberately reckless in not knowing that, [redacted]

[redacted]

439. On March 22, 2021, Defendants held a call with investors. During the call, Pourhassan stated:

> [H]ere is what we have done to move leronlimab forward for COVID-19 approval. . . . Please note that when you want to ask for emergency use authorization in United States, you will submit a request, so you file your request with the FDA. ***We did that, and we also told the FDA at the very beginning here is our executive summary. The FDA said that these results are good enough to allow you to continue with another trial to get more data for critical population. So, they did not shut us down, saying you don't have anything, they said there is reason to believe to go forward. We then filed a request for conditional EUA formally. We asked the agency to allow us to have a conditional emergency use authorization while we get more data from another trial which as we called it CD16.*** . . . So, in regards to FDA in United States, that's what we have. ***We formally have asked for conditional Emergency Use Authorization by our request with the FDA.***

440. Pourhassan's statement set forth in the above paragraph was materially false or misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing [redacted]

[redacted]

441. Likewise, Defendants' statements that "[t]he FDA said that these results are good enough to allow you to continue with another trial," "did not shut us down" or say "you don't have anything" and "said there is reason to believe to go forward" were materially false or misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

442. On March 30, 2021, Defendants' 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.

443. 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)***.

444. On April 1, 2021, Defendants issued a press release titled, "CytoDyn Files New Protocol with U.S. FDA for 4 Doses of Leronlimab for Critically Ill COVID-19 Patients with the Objective to Duplicate or Surpass ***82% Survival Benefit with P-Value of 0.0233 Originally Achieved from Two Weeks of Treatment in CD12 Trial With 2 Doses***." The press release quoted Pourhassan as follows: "our further analysis of ***the CD12 trial data demonstrated a statistically significant 82% reduction in mortality at 14 days for critically ill COVID-19 patients with 400% improvement in clinical outcome based on ordinal scale with discharge rate much better in leronlimab with p-value statistically significant***."

445. On April 7, 2021, Defendants held a conference call with investors. During the call, Pourhassan stated:

> In my humble opinion, there is no doubt that Leronlimab will be part of the future of COVID-19 therapies. This opinion of mine is justified for me from ***the fact that with one trial is severe to critical populations received data that indicated an 82 percent, 14-day survival benefit. Survival benefit was 82%with a statistically significant [p]-value of 0.0233. Change in clinical status for 14 days, on the basis of ordinal scale, 400 percent better, with a statistically significant [p]-value of 0.021.*** . . .

446. Defendants' statements set forth above in ¶¶ 442-45 collectively gave investors the misleading impression that (i) they had information, results, or statistically significant data to support the proof-of-concept or mechanism of action of leronlimab with respect to COVID-19; (ii) the CD12 results and/or data supported the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19; (iii) the statistically significant results in CD12's primary and secondary endpoints for the critically ill subgroup population and the related relative reduction of the risk of mortality were sufficient to support an EUA and/or additional

clinical trials in the U.S.; and (iv) the CD12 extension would generate data that could support the clinical benefit, efficacy, and safety of leronlimab to treat COVID-19 patients and/or an EUA for COVID-19. As set forth herein and in Section VIII.B, contemporaneous internal documentation clearly demonstrate that these statements were materially false and misleading, omitted material facts, or lacked a reasonable basis when made. By electing to speak publicly about these issues and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts.

447. Defendants' statements set forth above in ¶ 442 that "[l]eronlimab [d]ecreased [m]ortality . . . [w]ith [a] [s]tatistically [s]ignificant [p]-[v]alue . . . [a]mongst [c]ritically [i]ll COVID-19 [p]atients," "further statistical analysis of the critically ill population . . . revealed" that leronlimab + SoC "decreased mortality by 82% (p=.0233, N=62)," and "the CD12 trial data demonstrated a statistically significant 82% reduction in mortality . . . for critically ill COVID-19 patients" and show[ed]" "[a] clear benefit" "in the primary endpoint" for leronlimab + SoC and leronlimab + dexamethasone with a "28.1% (N=309, p=.0319)" and "26.0% (N=233, p.=.0552)" "relative risk reduction," respectively, were materially false and misleading, omitted material facts, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted]

448. On May 18, 2021, Defendants held a conference call with investors. During the call, Pourhassan stated:

> In today's call, I would like to talk about the FDA letter that was in the public domain yesterday, and also give updates of what we're doing to the shareholders and if anything has changed in the Company that we should tell the shareholders about. . . .
>
> So what I'm going to do right now to start this update call is I'm going to read everybody the FDA letter, the letter that we got after we asked for emergency use authorization. And they said no, you cannot have emergency authorization. This is what the letter said. There was four bullet points and I'm missing like some of the stuff that just general, but the points made, I'm reading. "Number one, 'as you acknowledged the trial did not meet its primary or secondary endpoints using the pre-specified analysis population (MITT population), M.I.T.T. is Modified Intent to Treat." . . . The next point that the FDA, I'm reading again the wording: "Therefore, we consider the additional analysis to be hypothesis generating, meaning that the analysis may inform the design of future clinical trials, but are not sufficient to support of the efficacy of leronlimab in the identified subgroups." So, here the FDA told us – you're not getting emergency use authorization, but we consider the additional analysis that you gave us to be hypothesis generating which warrants another trial, if we want for approval. Then the FDA said, the next point: "If you intend to continue development of leronlimab for the treatment of COVID-19 in a selected subgroup of the patient population included in CD12, please provide the division with your timeline for the development and initiation of a randomized double blinded adequate power trial in the selected patients group." And last point they make: "We are open to offering you a meeting to discuss the design of your proposed clinical trial after we have had the opportunity to review a detailed draft protocol of the proposed trial." . . . Did we say something that was different that the FDA letter said? The FDA letter said, and I read the first sentence: "FDA recognizes the substantial public interest in medicines that are helping studies for the prevention of treatment of COVID-19." So, they made a statement, and the statement is the MITT primary endpoint, secondary impact was not met.

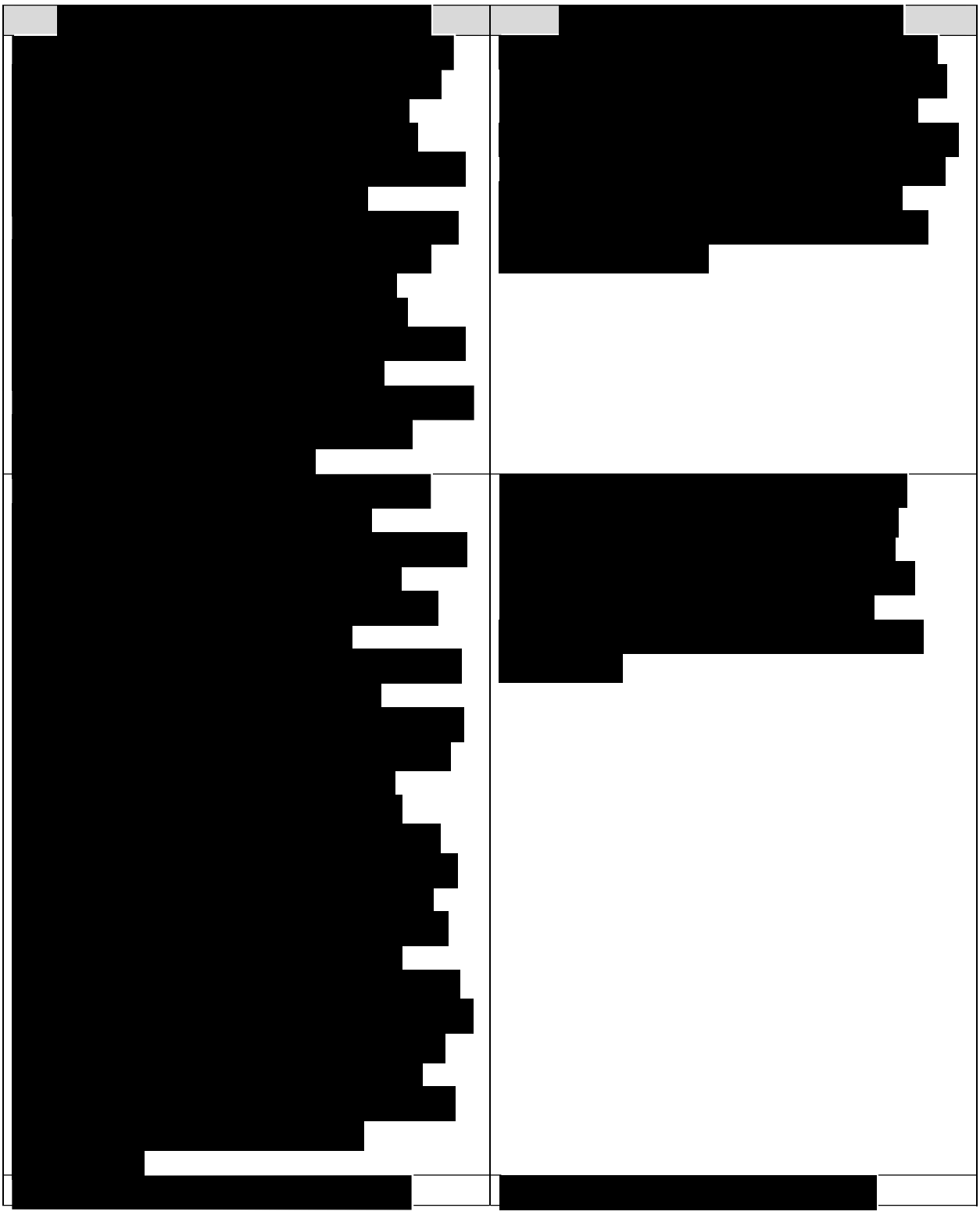
449. Pourhassan's statements set forth in the foregoing paragraph were materially false and misleading, omitted material information, or lacked a reasonable basis when made. The following chart compares Pourhassan's May 18, 2021 statements purporting to read from [redacted] with the actual content of the letter. Because Pourhassan represented that he was reading from FDA correspondence, he had a duty to disclose to investors all of the material information contained in the letter he chose to disclose, including the text identified below in blue, bold text. His failure to do so rendered his statements set forth above materially misleading when made:

Pourhassan's May 18, 2021 Statements	[redacted]
"I'm going to read everybody the FDA letter, the letter that we got after we asked for emergency use authorization, and they said, no, you cannot have emergency authorization. This is what the letters that there was four bullet point. And I'm missing some of this stuff that's just general . . . ."	[redacted]
"As you acknowledged, the trial did not meet its primary or secondary endpoints using the prespecified analysis Population (mITT population)."	[redacted] ysis population (mITT population)."
"Therefore, we consider the additional	[redacted]

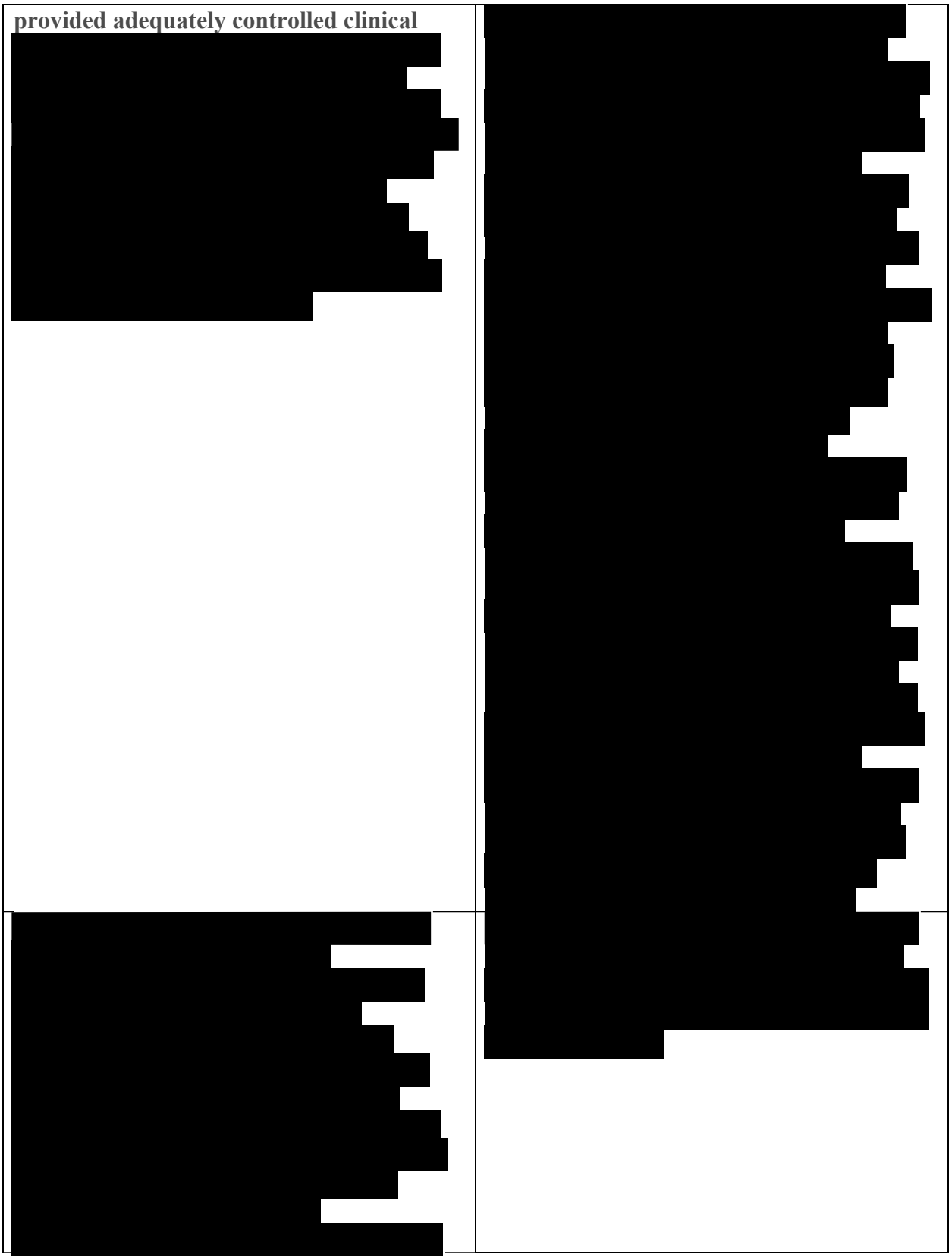
analysis to be hypothesis generating, meaning that the analysis may inform the design of future clinical trials, but are not sufficient to support of the efficacy of leronlimab in the identified subgroups."	[redacted]
"If you intend to continue clinical development of the leronlimab for the treatment of COVID-19 in a selected subgroup of the patient population included in CD12, please provide the Division with your timeline for the development and initiation of the randomized, randomized, double blinded adequate power trial in the selected patient population."	"If you intend to continue clinical development of leronlimab for the treatment of COVID-19 in a selected subgroup of the patient population included in CD12, please provide the Division with your timeline for the development and initiation of a randomized, double-blinded, adequately powered trial in the selected patient population."
"We are open to offer you a meeting to discuss the design of your proposed clinical trial after we have had the opportunity to review a detailed draft protocol of the proposed trial."	"We are open to offer you a meeting to discuss the design of your proposed clinical trial after we have had the opportunity to review a detailed draft protocol of the proposed trial."

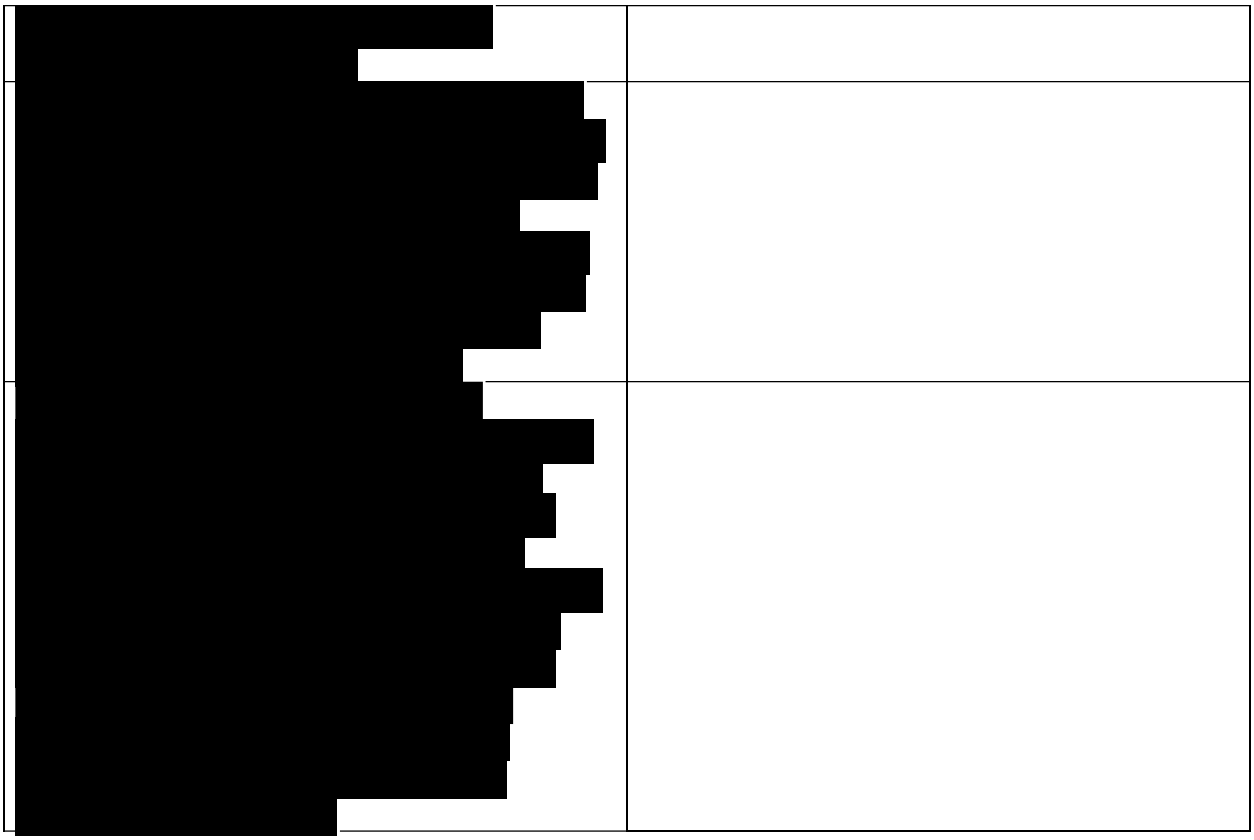
450. Moreover, Pourhassan's statements were materially misleading because he failed to disclose that [redacted] Given Pourhassan's statements that he was reading from FDA correspondence denying Defendants' EUA request and the letter from which he ultimately read expressly referenced and incorporated by reference [redacted]

[redacted] including at least the bolded, blue text in the below chart:



provided adequately controlled clinical





451. On September 15, 2021, Defendants participated in an Emerging Growth Conference after paying to be included. During the conference call, in response to a question regarding the "impact" an EUA in Brazil "could . . . have on the US FDA," Pourhassan stated:

> [S]o if we get approval EUA, what impact would it have on if the United States? I don't think it will have any, FDA United States was very clear. ***They saw the excitement that we saw in regards to critical ill population results***. The numbers are small and ***they were very right to tell us to do another trial anywhere in the world.*** And we're doing it. So I think FDA will continue to work with us as they have guided us . . . .

452. On September 22, 2021, Defendants participated in an Emerging Growth Conference after paying to be included. During the interview, Pourhassan stated:

> So in United States, we did a trial of 394 patients, which included severe and critically ill population . . . . [O]ur results were really strong. And therefore, the FDA United States says if you want to continue to develop leronlimab for critically ill population, then go ahead and do another trial and hit a primary endpoint and then we're done. . . .

453. Defendants' statements set forth in the above in the two preceding paragraphs were materially false or misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted] Likewise, Defendants' assertion that the FDA "saw the excitement we saw in regards to the critical[ly] ill population results were materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

454. Additionally, contrary to Defendants' assertions that the FDA told them to "go ahead and do another trial and hit a primary endpoint and then we're done" or "to do another trial anywhere in the world" [redacted]

[redacted]

Thus, Defendants' statements were materially false or misleading, omitted material facts, or lacked a reasonable basis when made.

455. On October 13, 2021, Defendants participated in an Emerging Growth Conference after paying to be included. During the conference, Pourhassan stated:

> First of all, covid-19 critically-ill population. And I also want to add to that that we will be filing the same protocol modified . . . to the United States FDA very quickly, because there are cases now in America that we could perhaps be able to enroll quickly, 200 patients interim analysis also that we will be filing that. At the same time, ***we might ask the agency for compassionate use*** . . . .

456. Defendants' statement set forth in the above paragraph was materially false and misleading, omitted material information, or lacked a reasonable basis when made because Defendants knew or were deliberately reckless in not knowing that [redacted]

[redacted]

457. Additionally, [redacted]

[redacted]

Accordingly, Defendants' assertion that CytoDyn might request compassionate from the FDA was materially false and misleading when made because [redacted]

458. Moreover, Defendants' statements created a misleading impression that there was some new reason to believe that a compassionate use request for leronlimab could be approved by the FDA. [redacted]

[redacted]

VI. DEFENDANTS ENGAGED IN A FRAUDULENT SCHEME TO PROMOTE AND OTHERWISE MANIPULATE THE MARKET CONCERNING CYTODYN STOCK IN VIOLATION OF RULE 10b-5 (a) AND (c)

459. 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).

460. Out of time, money, and excuses, the COVID-19 pandemic presented Defendants with a golden opportunity to engage 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.

A. Defendants Conduct a Scheme to Enrich Themselves Through Misleading Promotions

461. Prior to the start of the Class Period, Defendants had created an infrastructure to generate and capitalize on a buying frenzy manufactured by their false, misleading, and otherwise unsubstantiated statements and promotional efforts. Specifically, in order to artificially inflate the price of CytoDyn's common stock, Defendants issued more than 150 press releases, participated in frequent calls with investors, paid for and participated in interviews and presentations, engaged with stock promotion outlets to reiterate and amplify their statements, and themselves amplified or reiterated statements made by third parties on CytoDyn's website or in emails to investors.

462. Many, if not most, of these press releases, investor calls, and paid-for interviews and presentations contained materially false and misleading or otherwise unsubstantiated statements, touts, or promotions concerning the use of leronlimab to treat COVID-19. In fact, a significant amount of the information contained in these press releases and relayed during investor calls and paid-for interviews and presentations was never filed with the SEC and many of the events or milestones Defendants touted in their statements never came to fruition. Moreover, Defendants paid and directed stock promoter outlets like RedChip, Proactive Investors, Emerging Growth, and Mike Sheikh, among others, to reiterate and amplify statements, touts, or promotions in order to artificially inflate CytoDyn's stock price.

463. In order to cash in on their stock promotion fraud, Defendants issued themselves large numbers of stock options and warrants and exercised and sold millions of dollars' worth of shares of CytoDyn common stock at artificially inflated prices. Defendants also sought to secure additional capital and financing and to uplist to a national stock exchange on the basis of CytoDyn's stock price which had been artificially inflated by their stock promotion scheme.

464. **Press Releases**. During the Class Period, Defendants materially increased the number of press releases CytoDyn issued. [redacted] The Individual Defendants drafted, edited, reviewed, approved, and disseminated CytoDyn's press releases. The chart attached hereto as Exhibit A reflects their involvement in scores of such releases during the Class Period.

465. **Conference Calls with Investors**. Defendants held frequent calls with investors during the Class Period to discuss, among other topics, CytoDyn's potential COVID-19 indication.

During certain stretches, Defendants held calls several times a month or on an almost weekly basis irrespective of whether there was any information or data on which to update investors.

466. **Paid for Interviews and Presentations**. To further disseminate and amplify the information Defendants issued via press release or through investor calls, Defendants paid Proactive Investors for interviews of its executives and consultants and Wall Street Reporter and Emerging Growth for the ability to present to groups of investors about CytoDyn.

467. [redacted]

468. **Dissemination and Amplification of Third Party Media**. Defendants disseminated and amplified third party media, including articles, posts, and videos, about CytoDyn and, in particular, the Company's potential COVID-19 indication, by, among other tactics, featuring them on the Company's website, [redacted]

[redacted]

469. Defendants also placed links to third party materials supporting leronlimab as a potential COVID-19 treatment on the Company's website. In one instance, [redacted] The "article" claimed that leronlimab "is much more clinically efficacious than R[emdesivir]," "[m]ild-to-[m]oderate COVID-19 patients would experience much more beneficial improvement on leronlimab, with 90% efficacy (Grade A), than on Remdesivir, with 76% efficacy (Grade C)," and leronlimab "is absolutely safe as it has no SAE's related to it."[6] A link to the "article" was displayed prominently on CytoDyn's website [redacted] The link was removed that same day.

470. [redacted] an April 30, 2021 YouTube video titled "leronlimab, the little drug that could" that called "on the FDA to provide an emergency use authorization for leronlimab immediately" to [redacted]

[6]https://royberina.wordpress.com/2020/09/03/leronlimab-is-the-3-day-cure-for-mild-to-moderate-covid-patients-not-11-day-remdesivir/

[redacted]

[redacted]

471. Following the video's release, CytoDyn's common stock price rose 13% with a 77% increase in daily trading volume. Thereafter, the FDA sought to have the video removed from YouTube because it believed that it was "misleading when it comes to COVID-19." According to an email received via a FOIA request, the FDA told YouTube:

> 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 Filipino 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.

472. [redacted]

[redacted]

[redacted]

[redacted]

473. **Stock Promotion Outlets.** Despite CytoDyn's complete lack of revenues and massive receivables, Defendants paid hundreds of thousands of dollars to stock promotion outlets and greatly expanded the use of these services during the Class Period. Defendants paid these outlets to: (i) reissue and amplify CytoDyn's press releases; (ii) generate friendly interviews of Defendants that resembled materials generated by independent media outlets; (iii) host or otherwise moderate calls with investors and the audiences 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. Four outlets, Emerging Growth, Proactive Investors, RedChip Companies, and Wall Street Reporter, and one individual, Mike Sheikh were the most prolific services Defendants deployed before and during the Class Period.

B. How Defendants' Scheme Worked

474. The following represent examples of how each component of Defendants' fraudulent scheme or course of conduct combined to inflate CytoDyn's stock price during the Class Period.

475. During the first week of the Class Period, Defendants issued seven press releases. The first release, disseminated, Friday, March 27, 2020, touted "three-day results" for four of the seven eINDs and the second press release, issued 15 minutes later, claimed that the FDA had asked CytoDyn to file the CD12 protocol. Before the U.S. markets opened for trading on Monday, March 30, 2020, CytoDyn issued a third press release announcing three additional eINDs. Thereafter, on March 31, 2020, Defendants issued the fourth and fifth press release within fifteen minutes of each other announcing $15 million in financing and that the FDA had cleared the CD10 trial to proceed, respectively. Defendants issued a sixth press release on April 1, 2020 announcing that CytoDyn had submitted the CD12 protocol to the FDA and a seventh press release on April 2, 2020 with data for 8 eINDs. The chart set forth in Exhibit A sets forth each Defendants' role with respect to these press releases.

476. [redacted]

477. Once the press releases hit the wires, CytoDyn's paid promotional outlets, including Emerging Growth, Proactive Investors, and Wall Street Reporter, re-issued and/or amplified them on their respective websites.

478. Further, on March 27, March 31, and April 2, 2020 Pourhassan participated in interviews with Proactive Investors paid for by CytoDyn. Pourhassan also participated in two interviews with Yahoo! Finance and TD Ameritrade on April 1, 2020 and April 2, 2020, respectively. On March 31, 2020, Wall Street Reporter linked to a *TipRanks* article titled, "CytoDyn's Leronlimab Could Be an Answer to COVID-19" and subsequently provided a link to Pourhassan's April 1 Yahoo! Finance interview.

479. Following the press releases and paid-for interviews, as well as the Yahoo! Finance and TD Ameritrade appearances, various third party media outlets issued articles regarding CytoDyn. [redacted][7] [redacted]

480. [redacted]

481. 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 Pourhassan became CEO. On April 1, 2020, the price of CytoDyn's common stock closed over $3.00 for the first time since December 21, 2011.

482. Accordingly, [redacted]

[7] https://www.biocentury.com/article/304761 but needs to be put through WayBack Machine to work.

[redacted]

483. Defendants continued to execute their stock promotion scheme to great effect during the Class Period.

C. "Red Flags" of an Unlawful Scheme

484. 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* ¶¶ 89, 471; (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.

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

485. 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 often announcing events that ultimately did not happen, milestones that were not met, and actions that did not come to fruition.

486. Defendants hyped their purported efforts with respect to (i) the COVID-19 long hauler indication (which went nowhere following the conclusion of the CD15 trial); (ii) Phase 3 trial for mild-to-moderate COVID-19 patients (no protocol submitted to the FDA); (iii) Phase 3 trial for critically ill COVID-19 patients in the US, e.g., CD16 (Defendants stopped engaging with the FDA); and (iv) various submissions to Health Canada and U.K. MHRA (which went nowhere).

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

487. There has been a substantial increase in the authorized shares since 2018 without any meaningful increase in total current assets. In recent years, CytoDyn's BoD 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. At the same time, CytoDyn's total current assets have not meaningfully increased.

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

488. 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."

489. 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." Mulholland executed two of three certifications that cover the Class Period.

490. 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.

491. Here, for instance, while CytoDyn engaged Global Discovery Group (aka Emerging Growth) during this period, Emerging Growth's disclosures of such payment are non-existent, vague, or buried.

492. Further, just before and during the Class Period promotional outlets compensated by CytoDyn posted articles or reports, including articles or reports posted on March 23, 2020 (Emerging Grwoth article titled, "CytoDyn (OTCB: CYDY) Experiencing Viral Boom in Enrollment May Lead to a Presidential Podium Announcement"), June 12, 2020 (Emerging

Growth article titled "Adam Feuerstein's Fishing Expedition on CytoDyn (CYDY) Continues to Cast an Empty Net"), and July 30, 2020 (Emerging Growth article titled, "CytoDyn's (CYDY) 100% Above-Market Offering Stuns the Street"), 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.

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

493. 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.

494. 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.

VII. LOSS CAUSATION

495. 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.

496. Throughout the Class Period, Defendants' materially false and misleading statements and omissions alleged above in Section V and scheme, artifice, or device intended to deceive and/or 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. As a result of Defendants' materially false and misleading statements, omissions of material facts, and fraudulent scheme and/or course of conduct, CytoDyn's common stock traded at artificially inflated prices during the Class Period.

497. Relying on the integrity of the market price for CytoDyn common stock and public information relating to CytoDyn, Plaintiffs and other Class members purchased or otherwise acquired CytoDyn common stock at prices that incorporated and reflected Defendants' misrepresentations and omissions of material fact and fraudulent scheme and/or course of conduct alleged herein. As a result of their purchases or acquisitions of CytoDyn's common stock during the Class Period at artificially inflated prices and the removal of that inflation upon the disclosures set forth in Section VII, *infra*, Plaintiffs and other Class members suffered economic loss, or damages, under the federal securities laws.

498. Defendants' false and misleading statements, material omissions, and fraudulent scheme and/or course of conduct had their intended effect, directly and proximately causing CytoDyn common stock to trade at artificially inflated prices during the Class Period, trading as high as $10.00 per share in June 2021. Those misrepresentations and omissions of material fact or fraudulent scheme and/or course of conduct that were not immediately followed by an upward movement in the price of CytoDyn's common stock served to maintain the price of CytoDyn's common stock at an artificially inflated level.

499. Had Defendants been truthful about the state of CytoDyn's efforts to obtain approval for leronlimab to treat HIV or COVID-19 and/or not engaged in a fraudulent scheme and/or course of conduct, Plaintiffs and other Class members would not have purchased or otherwise acquired their CytoDyn common stock at the artificially inflated prices at which they traded. It was entirely foreseeable to Defendants that misrepresenting and concealing material facts from the public and/or engaging in a fraudulent scheme and/or course of conduct would artificially inflate the price of CytoDyn common stock. The economic losses (i.e., damages suffered by

Plaintiffs and other members of the Class) were a direct, proximate, and foreseeable result of Defendants' materially false and misleading statements and omissions of material fact and/or fraudulent scheme and/or course of conduct.

500. Plaintiffs and other Class Members suffered actual economic loss and were damaged when the material facts and/or foreseeable risks concealed or obscured by Defendants' misrepresentations and omissions and/or fraudulent scheme and/or course of conduct were partially revealed and/or materialized through the disclosure of new information concerning CytoDyn on the following dates: May 4, 2020, July 13, 2020, September 16, 2020, March 5-6, and 8, 2021, May 17, 2021, and March 30, 2022.

A. May 4, 2020

501. 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 Highly 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.

502. 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 million shares.

503. The material, negative news about the fact that the HIV BLA submitted on April 27, 2020 did not include the "clinical datasets" and would not be "complete" until May 11, 2020

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. July 13, 2020

504. Prior to trading 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 July 13, 2020 Press Release referred to the HIV BLA that CytoDyn had submitted to the FDA in April and May 2020. In a conference call following the close of trading on July 13, 2020, CytoDyn confirmed that the FDA requested more information regarding the HIV BLA via a Refuse to File letter.

505. 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 more than 21 million shares.

506. The sharp market price decline was widely understood by investors and market watchers to relate to the announcement of CytoDyn's receipt of a Refuse to File letter from the FDA. 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," reporting that "Shares $CYDY fell 21.99% to $3.69" and stated: "In a press release issued in early June announcing a HIV 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." Likewise, a July 16, 2020 article posted to *Seeking Alpha* titled, "CytoDyn's BLA Blues" noted "Monday morning (7/13/20) greeted CytoDyn investors with a step 2 [out of four steps for HIV approval] hiccup and a falling stock price" and confirmed that the July 13, 2020 Press Release "had a predictable impact on the share price."

507. 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 described the receipt of the RTF letter as "a setback that could delay a decision [on leronlimab] for months, if not years" and claimed that the RTF letter is "the most damning evidence yet that CEO Nader Pourhassan and other company executives might be misleading investors." The article continued:

> 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.
>
> * * *
>
> 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."

508. The highly value-relevant negative news—CytoDyn's receipt of a Refuse to File letter from the FDA because the HIV BLA was not complete—surprised investors and partially corrected the impact of Defendants' fraud.

509. 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. September 16, 2020

510. On September 16, 2020, after the close of the market, Defendants held a conference call with investors (the "September 16, 2020 Conference Call").

511. Prior to the September 16, 2020 Conference Call, Defendants had informed investors on August 12, 2020 and again on August 17, 2020 that they had "request[ed]" EUA for mild-to-moderate COVID-19 patients based on the results of CD10. Additionally, prior to the September 16, 2020 Conference Call, Defendants had confirmed in CytoDyn's August 14, 2020 FY20 Form 10-K that the Company expected to resubmit the BLA by the end of calendar year 2020. Defendants also had received from the FDA nonpublic written responses to their questions concerning the HIV BLA and the RTF letter on September 1, 2020 and participated in an informal teleconference with the FDA regarding the re-submission of the HIV BLA on September 8, 2020.

512. On September 10, 2020, Defendants issued a press release entitled, "CytoDyn to Hold Conference Call on September 16 to Provide Update on Discussions with FDA and MHRA for COVID-19 and FDA Meeting on BLA Filing," which alerted investors that "Dr. Dhody will discuss the very successful FDA meeting concerning CytoDyn's upcoming HIV BLA submission" among other topics. The same release also announced the September 16, 2020 Conference Call and stated that "CytoDyn will [] provide an update on the ongoing discussions with the FDA . . . for leronlimab as a treatment for COVID-19."

513. During the September 16, 2020 Conference Call, Dr. Dhody provided an update on the Company's meeting with the FDA on September 8, 2020 regarding the HIV BLA. According to Dr. Dhody, "the purpose of the meeting [wa]s to come to agreement with the agency [FDA] for the submission of efficacy data to support 700 mg dose." More specifically, Dr. Dhody explained

that the "FDA wants to see the data from an ongoing monotherapy study [CD03] to support . . . not only the safety, but also the efficacy of 700 mg dose from the CD03" trial. Dr. Dhody further claimed that the issue with the HIV BLA was not "the lack of expertise" but "the lack of existing underlying data from the 700 mg dose from an ongoing clinical trial [CD03]." Dr. Dhody, however, asserted that despite this, CytoDyn has "all the level of information that is needed to be submitted to" the FDA and "all the [unintelligible] data . . . to make a successful submission to" the FDA "and get the marketing approval for [the] HIV indication." Following Dr. Dhody's explanation, an analyst from H.C. Wainwright asked Defendant Pourhassan about "a timeframe" for "resubmit[ting] the BLA," to which Defendant Pourhassan responded "We do not want to give a timeframe at this time."

514. In other words, as a result of the September 16, 2020 Conference Call, investors learned for the first time that the HIV BLA did not include efficacy data for the 700 mg dose from the CD03 trial because CytoDyn did not have it at the time of the HIV BLA submission in April and May 2020 and that it was the lack of data, not a "lack of expertise," that led to the need to resubmit the HIV BLA. Likewise, investors learned that despite Dr. Dhody's assertions that CytoDyn and the FDA were in agreement as to what data needed to be submitted with a revised HIV BLA and CytoDyn purportedly had all the data to make successful submission to the FDA, the Company would no longer be able to resubmit the HIV BLA before the end of calendar year 2020 as Defendants had previously represented.

515. With respect to the CD10 trial and the fate of CytoDyn's request for EUA for mild-to moderate COVID-19 patients during the September 16, 2020 Conference Call, Defendant Pourhassan informed investors that the U.S. FDA wanted "to see CD12 interim results" before taking any action on leronlimab. Pourhassan also disclosed for the first time that CytoDyn "did not submit a formal letter to the FDA saying we want to get the emergency use authorization" for mild-to-moderate COVID-19 patients but rather "asked [the FDA] for their opinion and they were not positive about it." Pourhassan likewise confirmed that "we haven't filed officially yet" with

the FDA the EUA for mild-to-moderate COVID-19 patients. Pourhassan further stated, the "FDA is telling us right now, mild to moderate is not going to get emergency use access, that's their opinion and they recommend for us not file for that." As a result, Pourhassan confirmed, "I'm not optimistic at all about getting emergency use authorization from [the] FDA" for mild-to-moderate COVID-19 patients.

516. As a direct result of Defendants' disclosures, on the next trading day, September 17, 2021, the price of CytoDyn's common stock fell by $0.61 per share—over 15%—from a close of $4.03 on September 16, 2020 to a close of $3.42 on September 17, 2020 on high trading volume of nearly 9 million shares.

517. Market observers commented upon and understood the combined effective of Defendants' disclosures during the September 16, 2020 Conference Call: CytoDyn was nowhere near an approval for leronlimab in any indication, and therefore would not be able to recognize any revenue for the foreseeable future. For example, on September 18, 2020 analyst H.C. Wainwright issued a report titled, "Emergency Approval for COVID-19 Requires Additional Data; Reiterate Neutral. Under the headline "**No leronlimab immediate-term emergency approval in COVID-19**," H.C. Wainwright confirmed its belief that "the company is unlikely to receive emergency approval of leronlimab for COVID-19 in the immediate term." Additionally, under the headline, "**HIV BLA to be resubmitted**," H.C. Wainwright noted that although "[m]anagement indicated that CytoDyn now has all the data required by the FDA for resubmission . . . management has decided not to disclose a time frame for the BLA resubmission at this time."

518. [redacted]

519. [redacted]

520. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

521. The highly-value relevant negative news—that Defendants would not obtain approval of leronlimab in the immediate term, either through the resubmission of the HIV BLA and or through an EUA for mild-to-moderate COVID-19 patients—surprised investors and partially corrected the impact Defendants' fraud. 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. March 5, March 6, and March 8, 2021

522. On Friday, March 5, 2021, after the close of the market, CytoDyn issued a press release 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," (the "March 5, 2021 Press Release"). On Saturday, 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," (the "March 6, 2021 Press Release"). The press releases purported to address the results of leronlimab's Phase 2b/3 Trial (CD12) for treating severe and critical COVID-19 patients. The March 5, 2021 Press Release did not mention whether the study's primary endpoint had been reached, while the March 6, 2021 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.

523. 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 more than 21 million shares.

524. Market observers tracking the news reacted to CytoDyn's negative disclosure. 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."

525. Similarly, in a pre-market March 8, 2020 article posted on *Seeking Alpha* titled "CytoDyn: Parsing Failure," the author reported that "CD12 leronlimab Phase 3 trial on COVID-19 severe-to-critical patients failed," noting that "[e]ven with a cherry-picked adjustment (out of many possible adjustments, since the treatment and placebo arms won't be perfectly balanced on many measures), Leronlimab still failed all endpoints, primary and secondary." According to the

author, "CytoDyn tried to snatch victory from the jaws of defeat, using the oldest trick in the 'dubious biotech' book," "[a] post hoc analysis" or "an attempt, after the fact, to find patterns in the results of testing a hypothesis, after the initial results confirming or (more typically) denying the hypothesis are known." However, as the article makes clear, FDA "doesn't look favorably upon" the use of post hoc analyses or "data-dredging" to establish efficacy.

526. 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.

527. 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.

528. 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.

529. 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." In a March 11, 2021 article posted on *Seeking Alpha* titled, "CytoDyn: Understanding Further," the author addressed the March 8, 2021 Form 8-K noting that "[s]ome might still hang on to the fallacious post hoc analysis that we already knew the FDA would not accept as a basis for any kind of approval." In a March 12, 2021 article posted to *Seeking Alpha* titled, "CytoDyn: Preparing For Capitulation After A Successful Failure," the author noted that "the overall [CD12] study was perceived as a failure by investors" and "[a]s a result, the share price has plummeted and investor sentiment has gone with it."

530. The highly value-relevant negative news that the CD12 trial had failed to meet any of its pre-specified endpoints surprised investors and partially corrected the impact of Defendants' fraud. 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.

E. May 17, 2021 Disclosure

531. On May 17, 2021, the FDA publicly issued a "Statement on Leronlimab." Specifically, the FDA stated:

> 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" . . . . 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 . . . .

532. By issuing the May 17 FDA Statement, the FDA publicly refuted and rejected Defendants' repeated claims, implicit and explicit, to the market that leronlimab was safe and efficacious to treat mild-to-moderate or severe-to-critically ill COVID-19 patients based on the data from the eINDs, CD10, and CD12 that Defendants' repeatedly touted to investors.

533. 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.

534. Industry observers noted the FDA's unusual, severely negative response to CytoDyn, and the fact that it directly contradicted Defendants' repeated claims about the data from the eINDs and the CD10 and CD12 trials and the likelihood of FDA approval for 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.

535. The highly value-relevant negative news contained in the May 17 FDA Statement surprised investors and partially corrected the impact of Defendants' fraud. 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.

F. March 30, 2022

536. On March 30, 2022, following the conclusion of trading, CytoDyn issued a press release titled, "CytoDyn Announces Partial Clinical Hold of HIV Program and Full Clinical Hold

of COVID-19 Program" (the "March 30, 2022 Press Release"). The March 30, 2022 Press Release announced that the FDA had "placed a partial clinical hold on its HIV program and a full clinical hold on its COVID-19 program in the United States." CytoDyn further disclosed that it was "in the process of reevaluating the timing of its HIV BLA resubmission" and that "[t]he partial clinical hold on the HIV program impacts patients current enrolled in extension trials," noting that "these patients will be transitioned to other available therapeutics."

537. As explained in the Company's FY21 Form 10-K, "[a] clinical hold is an order issued by the FDA to the sponsor to . . . suspend an ongoing investigation" that is typically issued "[f]ollowing the commencement of a clinical trial under an IND." Pursuant to 21 C.F.R. §312.42, the FDA "may place a proposed or ongoing Phase 2 or 3 investigation on clinical hold if it finds that": (i) patients "are or would be exposed to an unreasonable and significant risk of illness or injury"; (ii) "[t]he clinical investigators named in the IND are not qualified"; (iii) "[t]he investigator brochure is misleading, erroneous, or materially incomplete"; or (iv) "[t]he IND does not contain sufficient information required under § 312.23 to assess the risks to subjects of the proposed studies." As further explained in the Company's FY21 Form 10-K, "[f]ollowing the issue of a clinical hold or a partial clinical hold, a clinical investigation may only resume once the FDA has notified the sponsor that the investigation may proceed." According to CytoDyn, "[t]he FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed or recommence."

538. The following morning, prior to the start of trading, CytoDyn held a conference call with investors to further explain the March 30, 2022 Press Release (the "March 31, 2022 Conference Call"). At the outset of the March 31, 2022 Conference Call, interim President Antonio Migalese, stated that, among other things, CytoDyn planned to do at least the following over "the next six months": "strengthen[] our clinical operations," "[a]ddress the concerns noted in the partial clinical hold letter received for HIV and the full clinical hold letter received for COVID-

19," "analyz[e] HIV data received from Amarex," and "revamp[] the timeline and activities needed for a successful BLA resubmission."

539. With respect to the clinical holds, Defendant Kelly stated:

> Now, regarding our full clinical hold on the US IND for covid-19 and the partial clinical hold on [the] IND for HIV. There have been no trials ongoing in the United States for COVID-19, we are not enrolling any patients at this time. We are currently not enrolling new patients for HIV and we're closing our long term HIV extension trials after obtaining data in some patients for over six to seven years. The FDA wants aggregated safety data across all indications as our prior C.R.O. was not aggregating safety data. We will correct this and we believe this is a solvable problem. We have contracted with the new pharmacovigilance C.R.O. to move forward, so we expect about eight to 12 week timeline and then we will seek advice from the FDA.

540. Additionally, Dr. Recknor stated: "Regarding the re-evaluation, the timelines, we're going to have a delay in the clinical activities [for leronlimab] while we are performing a pharmacovigilance evaluation through the new[ly] contracted CRO. Bond was posted with Amarex for the metrics and data was obtained for all of our trials, including [the] Trial Master File."

541. These disclosures confirm that CytoDyn received a partial and full clinical hold on its HIV and COVID INDs, respectively, because the FDA lacked data concerning at least the safety of leronlimab and CytoDyn was not in a position to immediately provide missing data and analysis to the FDA in support of its HIV and COVID-19 INDs either because the necessary data did not exist, had been in the possession of the Company's former CRO, Amarex, [redacted] or had not been analyzed. [redacted] This likewise had the effect of further delaying the HIV BLA resubmission, as disclosed by Defendants on March 30, 2022.

542. The partial and full clinical holds on the Company's HIV and COVID-19 INDs, respectively, also confirmed that CytoDyn could not conduct any further trials, including trials for critically ill or long hauler COVID-19 patients in the U.S., and was nowhere near approvals for HIV or any COVID-19 indication, including mild-to-moderate, severe or critically ill, or long hauler patients, and therefore any meaningful revenue from the sale of leronlimab. Additionally, CytoDyn's inability to further study leronlimab for any COVID-19 indication as a result of the full clinical hold likely was a consequence of Defendants' repeated misrepresentations of the data from the COVID-19 trials, as reflected in the May 17 FDA Statement and the February 11, 2022 Warning Letter.

543. In direct response to the March 30, 2022 Press Release and the March 31, 2022 Conference Call, on March 31, 2022, the price of CytoDyn's common stock fell by $0.11 per share—more than 22%—from a close of $0.48 on March 30, 2022, to a close of $0.37 on March 31, 2022 on high trading volume of more than 18 million shares.

544. 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.

545. 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.

VIII. ADDITIONAL ALLEGATIONS OF SCIENTER

546. 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 and/or course of conduct. *See supra* Sections VI.A-B. CytoDyn, through its management, consultants, 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 V 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 or Were Deliberately Reckless in Not Knowing That Their Statements Concerning the HIV BLA Were Materially False or Misleading When Made

547. Internal documents, including Defendants' communications with the FDA regarding the HIV BLA, demonstrate that Defendants knew their statements set forth in Section V.A regarding the HIV BLA were materially false or misleading when made.

548. **Pre-Class Period Scienter.** [redacted]

[redacted] As a result, Pourhassan knew or was deliberately reckless in not knowing [redacted]

549. [redacted] As a result, Pourhassan (and/or Kelly or Mulholland as noted herein) knew or was deliberately reckless in not knowing the information contained in the following FDA correspondence regarding the HIV BLA:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

g. [redacted]

h. [redacted]

i. [redacted]

j. [redacted]

k. [redacted]

550. [redacted] As a result, Pourhassan knew or was deliberately reckless in not knowing the information discussed during the meeting:

a. [redacted]

b. [redacted]

c. [redacted]

551. [redacted]

552. [redacted]

553. **April 27, 2020 HIV BLA Submission.** In a sworn declaration filed in *CytoDyn, Inc. v. Amarex Clinical Research, LLC*, No. 21-cv-2533, Dr. Kazempour stated that Amarex "warned" Pourhassan about the incomplete HIV BLA prior to its submission in April 2020. 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, attached to the Kazempour Decl., 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 Pourhassan's direction, Amarex submitted the incomplete and lacking [HIV] BLA to the FDA."

554. [redacted] As such, [redacted] Pourhassan knew or was deliberately reckless in not knowing that the HIV BLA was not complete as of April 27, 2020.

555. **July 8, 2020 RTF Letter**. [redacted]

556. **September 1, 2020 Letter and September 8, 2020 Teleconference**. [redacted] As such, Pourhassan and Kelly, as well as Dr. Dhody, knew or were deliberately reckless in not knowing

[redacted]

557. [redacted]

[redacted]

558. **Inventory Accounting**. [redacted]

[redacted]

559. By virtue of his receipt of at least the FDA correspondence set forth above, as well as his attendance at meetings with the FDA, including at least those identified above, Pourhassan knew or was deliberately reckless in not knowing that [redacted]

560. [redacted]

561. By virtue of their receipt of at least the FDA correspondence set forth above, and, in particular the FDA's July 8, 2020 RTF letter, Pourhassan, Mulholland, and Kelly knew or were deliberately reckless in not knowing that [redacted] In fact, the RTF letter made clear that CytoDyn had failed to submit the necessary safety and efficacy data to even allow the FDA to determine if the HIV BLA was complete prior to beginning its review in earnest.

562. [redacted]

563. By virtue of their receipt of at least the FDA correspondence set forth above, and, in particular the FDA's July 8, 2020 RTF letter, Pourhassan, Mulholland, and Kelly knew or were deliberately reckless in not knowing that [redacted] In fact, the RTF letter made clear that CytoDyn had failed to submit the necessary safety and efficacy data to even allow the FDA to determine if the HIV BLA was complete prior to beginning its review in earnest. Likewise, the RTF letter did, in fact, reject the HIV BLA as submitted, refusing to file it.

B. Defendants Knew or Were Deliberately Reckless in Not Knowing Their Statements Concerning COVID-19 Were Materially False or Misleading When Made

564. Internal documents, including Defendants' communications with the FDA regarding the COVID-19 IND, the COVID-19 eINDs, three COVID-19 trials (CD10, CD12, and CD15), and potential COVID-19 EUAs, demonstrate that Defendants knew or were deliberately reckless in not knowing that their statements set forth in Section V.B regarding COVID-19 were materially false or misleading when made and that they were engaged in a fraudulent scheme and/or course of conduct as set forth in Section VI.

565. **Mechanism of Action and Proof-of-Concept in COVID-19.** Pourhassan and Kelly, as well as Drs. Lalezari and Patterson, and Kazempour knew or were deliberately reckless in not knowing that [redacted]

566. Pourhassan, as well as Drs. Dhody, Lalezari, and Patterson also knew or were deliberately reckless in not knowing that [redacted]

Pourhassan and Kelly and Drs. Dhody, Lalezari, and Patterson likewise knew or were deliberately reckless in not knowing that, [redacted]

[redacted] Mulholland knew or was deliberately reckless in not knowing [redacted]

567. [redacted] On June 1, 2020, as at least Pourhassan and Drs. Dhody and Lalezari knew or were deliberately reckless in not knowing that [redacted]

568. Additionally, at least Pourhassan and Drs. Dhody and Lalezari knew or were deliberately reckless in not knowing that [redacted] In other words, Defendants knew or were

deliberately reckless in not knowing that [redacted]

569. Moreover, [redacted]

570. [redacted]

571. Additionally, [redacted]

[redacted]

572. [redacted]

573. **eIND Results and Compassionate Use.** Defendants also knew or were deliberately reckless in not knowing that [redacted] For instance, Pourhassan and Kelly, as well as Drs. Dhody, Lalezari, and Patterson knew or were deliberately reckless in not knowing that, [redacted] Pourhassan, Kelly, and Mulholland and Dr. Dhody also knew or were deliberately reckless in not knowing that, [redacted]

574. [redacted]

575. [redacted]

576. [redacted]

577. In addition to the FDA, Defendants knew or were deliberately reckless or not knowing that [redacted]

578. Further, at the same time that [redacted]

[redacted]

579. [redacted]

580. **CD10.** Pourhassan and Kelly, as well as Drs. Dhody, Lalezari, and Patterson, knew or were deliberately reckless in not knowing that [redacted] Pourhassan, Kelly, and Mulholland, as well as Dr. Dhody, likewise knew or were deliberately reckless in not knowing that, [redacted]

[redacted]

581. [redacted] Pourhassan and Kelly and Drs. Dhody and Lalezari knew or were deliberately reckless in not knowing that [redacted] As a result, Dr. Lalezari told Pourhassan, Kelly, and Dr. Dhody knew or were deliberately reckless in not knowing [redacted]

582. [redacted] Pourhassan, Kelly, and Mulholland, as well as Drs. Dhody and Lalezari knew or were deliberately reckless in not knowing that [redacted]

583. Defendants also knew or were deliberately reckless in not knowing that [redacted] *See* Multiple Endpoints in Clinical Trials: [Draft] Guidance for Industry at 8. Defendants likewise knew or were deliberately reckless in not knowing

that the FDA defined post hoc analyses premised upon a post hoc adjustment to the study's design features "to attempt to elicit a positive study result from a failed study" as "data-dredging." *Id.* According to the FDA, such analyses "can be biased because the choice of analyses can be influenced by a desire of success" and "by themselves cannot establish effectiveness." *Id.*

584. Defendants knew or were deliberately reckless in not knowing that [redacted] Defendants knew or were deliberately reckless in not knowing that [redacted]

585. By September 5, 2020, at least Pourhassan knew or was deliberately reckless in not knowing that, [redacted] Likewise, at least Pourhassan knew or was deliberately reckless in not knowin that [redacted] And critically, at least Pourhassan was aware that [redacted]

586. Additionally, by no later than September 9, 2020, Pourhassan and Kelly, as well as Drs. Dhody and Lalezari, knew or were deliberately reckless in not knowing that [redacted] Likewise, Pourhassan and Kelly and Dr. Dhody knew or were deliberately reckless in not knowing that by [redacted]

[redacted] Additionally, Pourhassan, Kelly and Dr. Dhody knew or were deliberately reckless in not knowing that [redacted]

587. [redacted]

588. [redacted]

589. [redacted]

590. [redacted]

591. **Class Period Misstatements and Omissions.** Defendants knew or were deliberately reckless in not knowing that [redacted]

592. [redacted]

593. [redacted]

594. [redacted]

[redacted]

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

595. 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"). While 6,050,000 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, 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.

596. As described in the verified *Alpha Ventures* complaint the December 19, 2019 BoD meeting and resulting December 2019 Awards as a "procedural sham" and "an outrageous act of collective self-dealing and blatant disregard for fiduciary obligations."

597. The December 2019 Awards were the subject of a lawsuit—*Alpha Ventures*—filed by Gould, Dockery, Caracciolo, and others derivatively on behalf of CytoDyn against 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 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.

598. On May 4, 2020, the BoD formed a special litigation committee ("SLC") to investigate the Alpha Ventures' claims. The SLC in turn adopted resolutions prohibiting 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."

599. 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.

600. On June 4, 2021, the Delaware Chancery Court approved the *Alpha Ventures* settlement, requiring 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 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.

601. Despite the Court's express concern, on October 20, 2021, CytoDyn awarded 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

602. During the Class Period, 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 HIV BLA and 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.

603. During the Class Period, 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. 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		
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		

DEFENDANT POURHASSAN					
Transaction Date	**Acquired/ Disposed**	**No. of Shares**	**Exercise Price**	**Sale Price**	**Proceeds**
4/30/2020	Disposed	2,219,837		$3.5312[8]	**$7,838,688.41**
5/1/2020	Disposed	1,399,685		$3.2644[9]	**$4,569,131.71**
5/4/2020	Acquired	30,933	$0.39		
5/4/2020	Disposed	1,201,652		$2.7904[10]	**$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**

604. During the Class Period, 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. Kelly's trades are set forth in the following chart:

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	--	

[8] 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.

[9] 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.

[10] 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	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**[11]	**$3,912,480**
TOTAL DISPOSED		**1,200,000**	**TOTAL PROCEEDS**		**$3,912,480**

605. During the Class Period, 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. Mulholland's trades are set forth in the following chart:

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[12]	**$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		

[11] 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.

[12] 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.

DEFENDANT MULHOLLAND					
Transaction Date	**Acquired/ Disposed**	**No. of Shares**	**Exercise Price**	**Sale Price**	**Proceeds**
12/18/2020	Disposed	**487,002**		$4.9516[13]	**$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[14]	**$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[15]	**$1,349,848.64**
12/22/2020	Disposed	**453,997**		$6.6146[16]	**$3,003,008.56**
12/22/2020	Disposed	**12,100**		$7.00	**$84,700.00**
TOTAL DISPOSED		**1,816,600**	**TOTAL PROCEEDS**		**$10,264,588.75**

606. 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

[13] 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.

[14] 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.

[15] 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.

[16] 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.

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, Pourhassan 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. 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.

607. 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, 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.

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

609. Leading up to and during the Class Period, CytoDyn underwent significant BoD 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.

610. **Dr. Pestell**. In 2018, CytoDyn purchased Dr. Pestell's biotechnology start-up, ProstaGene. 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. 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." Thereafter, Pourhassan engineered a CytoDyn BoD meeting at which Dr. Pestell was terminated for cause. Dr. Pestell sued CytoDyn and as part of a settlement shortly before trial, the Company issued a press release noting that "CytoDyn regrets Dr. Pestell's departure from the Company and the subsequent public statements made by its former CEO about Dr. Pestell."

611. Notably, Dr. Pestell's former company, ProstaGene, separately won a $7 million arbitration award against CytoDyn. The arbitration panel found, at the conclusion of the proceeding, that: (i) CytoDyn had proceeded with an FDA 510(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."

612. **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 BoD 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, 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.

613. **Dr. Rahman**. CytoDyn hired Dr. Rahman as the Company's Chief Scientific Officer in October 2020. [redacted] *See supra* ¶¶ 412-25. [redacted] Dr. Rahman himself made material misstatements and omissions on behalf of CytoDyn. *See supra* Section V.B.3. [redacted]

614. [redacted]

3. Pourhassan's Termination Supports a Strong Inference of Scienter

615. On January 25, 2022, CytoDyn announced that it had terminated Pourhassan as its CEO.

616. [redacted]

617. [redacted]

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

618. As discussed above, throughout the Class Period, Defendants Pourhassan, Mulholland, and Kelly each were in possession of material, nonpublic 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.

619. 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).

620. 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.

621. 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).

622. 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).

623. 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).

624. 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:

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

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

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

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

629. 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.

X. CLASS ACTION ALLEGATIONS

630. 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.

631. 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.

632. 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.

633. 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.

634. 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.

635. 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.

XI. FRAUD ON THE MARKET PRESUMPTION OF RELIANCE APPLIES

636. 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.

637. 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.

638. 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.

639. 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.

XII. INAPPLICABILTIY OF THE STATUTORY SAFE HARBOR

640. 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).

641. 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.

642. 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.

643. 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.

644. 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.

XIII. CAUSES OF ACTION

COUNT I

FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND SEC RULE 10b-5(b) AGAINST ALL DEFENDANTS

645. 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(b) promulgated thereunder, 17 C.F.R. § 240.10b-5, on behalf of Plaintiffs and all other members of the Class.

646. During the Class Period, Defendants, while in possession of material adverse, nonpublic 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.

647. 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.

648. 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.

649. 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.

650. 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.

651. 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.

652. 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.

653. 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 10(b) OF THE EXCHANGE ACT AND SEC RULE 10b-5(a) and (c) AGAINST ALL DEFENDANTS

654. 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) and (c) promulgated thereunder, 17 C.F.R. § 240.10b-5, on behalf of Plaintiffs and all other members of the Class.

655. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) 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 and (ii) 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.

656. During the Class Period, 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.

657. 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.

658. 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.

659. 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.

660. 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.

661. 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.

662. 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 III

FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

663. 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.

664. 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.

665. 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.

666. 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.

667. 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.

668. 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 IV

FOR VIOLATIONS OF SECTION 20A OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

669. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

670. 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.

671. 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."

672. 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.

673. 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.

674. 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.

675. Plaintiffs and other members of the Class have been damaged as a result of the violations of the Exchange Act alleged herein.

676. 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.

677. 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.

678. 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.

XIV. 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.

XV. JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Dated: June 24, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned attorney certifies that on the 24th day of June 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel on record in the matter. The version filed under seal will be served on all counsel on record via electronic mail, and the redacted version will be available for viewing on the docket.

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