UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Plaintiff,

v.

PROTHENA CORPORATION PLC, GENE G. KINNEY, TRAN B. NGUYEN, and SARAH NOONBERG,

Defendants.

COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

CLASS ACTION

JURY TRIAL DEMANDED

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counsel, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief are based upon, *inter alia*, counsel's investigation, which included review and analysis of: (a) regulatory filings made by Prothena Corporation plc ("Prothena" or the "Company") with the United States Securities Exchange Commission ("SEC"); (b) press releases, presentations, and media reports issued by and disseminated by the Company; (c) analyst reports concerning Prothena; and (d) other public information regarding the Company.

I. INTRODUCTION

1. This class action is brought on behalf of all persons or entities that purchased Prothena's publicly traded common stock between October 15, 2015 and April 20, 2018, inclusive (the "Class Period"). The claims asserted herein are alleged against Prothena and certain of the Company's senior executives (collectively, "Defendants"), and arise under Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5, promulgated thereunder.

2. Prothena is a development-stage biotechnology company. During the Class Period, Prothena's principal asset was NEOD001, a monoclonal antibody designed to treat amyloid light chain amyloidosis ("AL amyloidosis"), a debilitating disease that can lead to organ failure and death. This matter arises from Defendants misrepresentations and material omissions regarding NEOD001's clinical trial results and prospects for approval. Throughout the Class Period, Defendants cited the "best response" results of Prothena's ongoing Phase 1/2 clinical study of NEOD001 as evidence that the drug was effective, while withholding relevant trial data showing that NEOD001 was not an effective treatment for AL amyloidosis. In addition, Defendants made misleading comparisons of NEOD001's "best response" rates against prior studies that measured sustained responses after a specified period of time, and falsely told investors that Prothena's ongoing Phase 1/2 study provided a strong basis for late-stage Phase 2b and Phase 3 studies of NEOD001. In truth, the full Phase 1/2 study data demonstrated that NEOD001 was not an effective treatment for AL amyloidosis and did not provide an adequate basis for the late-stage Phase 2b and

Phase 3 studies.

3. The Class Period begins on October 15, 2015, when Prothena issued a press release announcing the start of its late-stage Phase 2b "PRONTO" study and the expansion of its ongoing Phase 1/2 clinical trial for NEOD001. The press release explained that the Phase 2b PRONTO study was "a global trial of NEOD001 in previously-treated patients with AL amyloidosis and persistent cardiac dysfunction." During the Company's October 15, 2015 conference call to discuss the launch of the PRONTO clinical trial, Prothena's then President and Chief Executive Officer, Dr. Dale Schenk ("Schenk"), highlighted to investors that the PRONTO trial was "informed by the results of our ongoing Phase 1/2 trial" presented earlier that year, which "showed that 60% of renal evaluable patients treated with NEOD001 achieved a response, and 57% of cardiac evaluable treated patients achieved a response." Schenk compared the Phase 1/2 results favorably to prior studies by third parties, stating that "these best response rates for both renal and cardiac evaluable patients were more than double the published historical rates reported in multiple AL amyloidosis studies."

4. On July 5, 2016, Prothena announced new data from the expanded Phase 1/2 clinical trial of NEOD001. This included "best response" rates of 53% in total cardiac patients and 63% in renal-evaluable patients. According to Prothena, the 53% cardiac best response rate and 63% renal best response rate "compared favorably" to cardiac response rates of 0% to 15% and renal response rates of 17% to 29% from available published historical data in patients previously-treated with chemotherapy or other plasma cell directed therapy, and were consistent with the Company's prior best response study results. During a conference call held that same day to discuss the new data, Schenk confirmed that these results went beyond "reassuring safety and tolerability findings" and demonstrated "improvements in all three organ systems measured in this study: cardiac, renal, and peripheral nerves." Also during the call, Defendant Dr. Gene Kinney ("Kinney"), the Company's then-Chief Operating Officer and Chief Scientific Officer, cited the new Phase 1/2 results as a proxy for the likely success of Prothena's late-stage studies, including the Phase 2b "PRONTO" study, by underscoring "the relevance of the new Phase 1/2 results to our ongoing late-stage studies."

5. Throughout the Class Period, Defendants continued to tout the interim results of the Company's Phase 1/2 study to create the impression that NEOD001 would obtain final approval after completion of its late-stage Phase 2b PRONTO and Phase 3 VITAL studies. For example, on September 12, 2016, during the Morgan Stanley Global Healthcare Conference, Defendant Tran B. Nguyen ("Nguyen"), the Company's Chief Financial Officer, stated that the "exciting findings" from the Phase 1/2 expansion study "has to go back to what does it say about PRONTO and VITAL." Analysts accepted Defendants' positive statements regarding NEOD001's efficacy and the Phase 1/2 study results, and viewed the Company's Phase 1/2 study results as indicative of the likely success of the ongoing Phase 2b and Phase 3 trials. For example, on December 5, 2016, a Credit Suisse analyst noted that the final Phase 1/2 study results helped "de-risk the ongoing PRONTO and VITAL studies."

6. In truth, Prothena's "best response" analyses did not present a fair representation of the efficacy of NEOD001, particularly when compared to prior studies. What Prothena referred to as the "best response" rate was selected by the Company from among all the data points in their study. After cherry-picking the best response among the available data points for each patient, Prothena then compared that result to studies that used a single data point at the end of a pre-determined length of time, creating a false impression that NEOD001 was effective. Prothena never disclosed the full results of its Phase 1/2 testing – namely, the month-to-month response rate of each patient during the study – which would have permitted investors to conduct a fair comparison against the historical data.

7. On April 23, 2018, before the market opened, Prothena stunned investors by announcing that it was ending all development of NEOD001 after data from its Phase 2b PRONTO trial showed that NEOD001 failed to reach either its primary or secondary endpoints, and was substantially less effective than a placebo. In response to this news, Prothena stock fell 69%.

II. JURISDICTION AND VENUE

8. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5. This Court has jurisdiction over the subject matter of this action pursuant to

28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

9. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Prothena maintains its United States headquarters in South San Francisco, California, which is situated in this District, conducts substantial business in this District, and many of the acts and conduct that constitute the violations of law complained of herein, including dissemination to the public of materially false and misleading information, occurred in this District. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

Prothena securities on the NASDAQ Stock Market ("NASDAQ") at artificially inflated prices during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

11. Defendant Prothena is incorporated in Ireland with its U.S. operations headquartered in the city of South San Francisco, California. The Company's common stock trades on the NASDAQ under ticker symbol "PRTA." Prothena currently has over 39 million shares of stock outstanding.

12. Defendant Kinney served as President, Chief Executive Officer, and a Director at Prothena since September 2016. Prior to that, Kinney served as the Company's Chief Operating Officer and Chief Scientific Officer since the Company's founding in 2012.

13. Defendant Nguyen was, at all relevant times, Prothena's Chief Financial Officer. Nguyen joined Prothena as its Chief Financial Officer in 2013.

14. Defendant Sarah Noonberg, M.D., Ph.D. ("Noonberg") was Prothena's Chief Medical Officer from May 16, 2017 until February 2, 2018.

15. Defendants Kinney, Nguyen, and Noonberg are also collectively referred to

hereinafter as the "Individual Defendants." The Individual Defendants, because of their positions with Prothena, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each of the Individual Defendants was provided with copies of the Company's reports and press releases 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. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading.

IV. BACKGROUND

16. Prothena is a development-stage biotechnology company. During the Class Period, the Company's value was largely derived from its principal asset, NEOD001, an antibody designed to treat AL amyloidosis, a rare, progressive and typically fatal disease involving the heart, kidneys, and other vital organs. According to Prothena, there are no approved treatments for AL amyloidosis and there is a large unmet need for therapies that focus on improving vital organ function in patients with this debilitating disease.

17. Antibodies similar to NEOD001 intended to target AL amyloidosis have been available since at least 2000, but have performed poorly in clinical testing. Among other things, AL amyloid deposits are too diverse for a single antibody to work consistently across patient populations, and organ-specific obstruction have hindered the ability of AL amyloid antibodies to achieve meaningful responses. Moreover, radioimaging studies have shown that even where candidate drugs appeared to have meaningful responses, *i.e.*, binding between antibodies and amyloid deposits somewhere in the body, there is no effect on AL amyloid deposits in the heart, kidneys, or other vital organs.

18. Prothena claimed that its AL amyloidosis antibody, NEOD001, had unique characteristics that made it a potential cure for the disease. In 2012, the U.S. Food and Drug Administration ("FDA") granted NEOD001 "orphan drug" status and, in December 2014, granted

NEOD001 "Fast Track" designation. A drug program with Fast Track designation permits early and frequent communications with the FDA in the development and review of the candidate, potentially leading to faster drug approval.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS CAUSE SUBSTANTIAL LOSSES TO INVESTORS

19. The Class Period begins on October 15, 2015, when Prothena issued a press release announcing start of its late-stage Phase 2b "PRONTO" study for NEOD001 and the expansion of its ongoing Phase 1/2 study. According to the press release, the PRONTO study was a global, multi-center, randomized, double-blind, placebo-controlled clinical trial for NEOD001 in previously-treated patients with AL amyloidosis and persistent cardiac dysfunction. The press release described the Phase 2b PRONTO study to investors as follows:

> The global, multi-center, randomized, double-blind, placebo-controlled Phase 2b trial further exemplifies Prothena's commitment to provide disease-modifying therapeutic alternatives for patients suffering from AL amyloidosis. The trial is designed to enroll approximately 100 patients with a primary diagnosis of AL amyloidosis and persistent cardiac dysfunction despite previous treatment with off-label, plasma cell directed therapy. Patients will be randomized on a 1:1 basis to receive 24 mg/kg of NEOD001 or placebo via infusion every 28 days.
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> The primary endpoint is NT-proBNP best response as measured over 12 months. Secondary endpoints include evaluations of Short-form 36 (SF-36, quality of life measure), six-minute walk test, and renal function as assessed by proteinuria. Prothena designed the study with 80% power to detect a difference of 26.5% in NT-proBNP best response rate between the treatment and placebo groups with a two-sided alpha of 0.05.

20. At that time, in addition to the ongoing Phase 1/2 study, Prothena had another late-stage trial of NEOD001 underway - the Phase 3 "VITAL" study. According to the Company, the VITAL study was a multi-center, randomized, double-blind, placebo-controlled clinical trial in patients with AL amyloidosis that was intended to evaluate NEOD001 in newly-diagnosed, treatment-naïve patients. Prothena's press release asserted that Prothena's new Phase 2b PRONTO study, when combined with the ongoing Phase 1/2 study, could expedite the candidate drug's approval: "[t]he PRONTO trial was designed to align with feedback from the European Medicines Agency (EMA) related to The VITAL Amyloidosis Study, a global Phase 3 registrational trial. When combined with data from the ongoing NEOD001 Phase 1/2 trial, the PRONTO trial has the

potential to expedite patient access."

21. Also on October 15, 2015, during the Company's conference call with analysts and investors to explain the new study, Schenk cited the Phase 1/2 trial results as a proxy for the success of the late-stage studies stating, "the PRONTO trial was also informed by the results of our ongoing Phase 1/2 trial presented at both the American Society for Clinical Oncology and the European Hematology Association conferences earlier this year." Schenk also said during this call that "[t]hese data showed that 60% of renal evaluable patients treated with NEOD001 achieved a response, and 57% of cardiac evaluable treated patients achieved a response." Finally, Schenk compared the recent Phase 1/2 data to prior historical test results, stating that these "best response rates for both renal and cardiac evaluable patients were more than double the published historical rates reported in multiple AL amyloidosis studies."

22. On February 8, 2016, at the Biotechnology Industry Organization CEO & Investor Conference, Schenk continued to highlight to investors the "very good overall cardiac response rate" of 57% from the NEOD001 Phase 1/2 trial, and "renal response rate" of 60% that was "way above what any of the typical studies currently show." Schenk emphasized that the Phase 1/2 results were "encouraging" and "of course, as a result, we've gotten into the – set up the phase 2B and the phase 3s."

23. On February 11, 2016, at the Leerink Partners Global Healthcare Conference, Defendant Kinney assured investors that Phase 1/2 participants were improving, stating that these patients "had sufficient cardiac involvement that we could look for potential improvement after intervention with NEOD001 and 57% of those patients showed improvement based on predefined criteria." Defendant Kinney further linked Phase 1/2 results as a barometer for the ongoing late-stage studies: "yes, we think about the program obviously in the totality and clearly we think about how the Phase 1/2 derisks first our Phase 2b study, which is our PRONTO study and then further how PRONTO, as well as the phase 1/2 derisks the Phase 3 study."

24. On February 18, 2016, Prothena issued a press release, which was also filed with the SEC on Form 8-K, announcing the Company's financial results for the fourth quarter 2015 and full year 2015. Schenk is quoted in the press release highlighting the "encouraging" clinical results

from the Company's NEOD001 Phase 1/2 trial, stating that NEOD001 Phase 1/2 patients, "achieved more than double the cardiac and renal biomarker responses when compared to historical data in patients treated solely with off-label standard of care."

25. On February 25, 2016, Prothena filed with the SEC its annual report on Form 10-K for the year ended December 31, 2015. In its 2015 Form 10-K, Prothena favorably compared the NEOD001 test results for the Phase 1/2 study to historical studies: "In June 2015, we reported results from the ongoing Phase 1/2 study that showed 8 of 14 cardiac-evaluable patients (57.1%) treated with NEOD001 demonstrated a cardiac response, defined as more than 30% and 300 pg/mL decrease in levels of NT-proBNP from baseline and the remaining 6 patients (42.9%) achieved stable disease… 57.1% cardiac best response rate compares favorably with the expected cardiac best response rate of a 26.5% from historical data in patients treated solely with off-label standard of care (Comenzo, *et al.*, Leukemia. 2012; 26:2317-2325)."

26. As part of the March 11, 2016 Future Leaders in the Biotech Industry conference, Prothena produced a written presentation which reiterated the results of the Phase 1/2 trial, specifically the "best response" results of 57% and 60% for cardiac and renal patients, respectively. Additionally, Prothena stated in this presentation that the cardiac and renal response rates from its Phase 1/2 study "were more than double historical rates of 26.5% (cardiac) and 24% (renal) reported in AL amyloidosis studies."

27. Then, on July 5, 2016, Prothena issued a press release announcing new data from its expanded Phase 1/2 clinical trial of NEOD001. According to the July 5, 2016 press release, which was filed with the SEC on Form 8-K, the new Phase 1/2 data showed "best response rates of 53% and 63%" in cardiac and renal-evaluable patients, which were "consistent with those previously reported." Additionally, Prothena stated in the press release that these rates "compare favorably" to response rates in "available published historical data in patients previously-treated with plasma cell directed therapy." Schenk is quoted in the press release as stating "[w]e now have a robust data set of nearly 70 patients that informs our ongoing NEOD001 clinical development program" adding that the results "increase our confidence in the design and powering assumptions for both the PRONTO and VITAL studies."

28. On a conference call with analysts and investors held on July 5, 2016, to discuss the new Phase 1/2 study results, Defendant Kinney commented on the relevance of the results to the PRONTO and VITAL studies. Regarding PRONTO specifically, Defendant Kinney stated: "I would like to comment on the relevance of the new Phase 1/2 results to our ongoing late-stage studies…. the consistency of the results from the larger patient pool we are reporting today increases our confidence in the initial design and powering of PRONTO."

29. As part of the July 5, 2016 conference call to discuss new Phase 1/2 test results, Prothena produced a written presentation which reiterated the results of the trial, specifically the "best response" results of 53% and 63% for cardiac and renal patients, respectively, and an 82% response rate for neuropathy patients. Additionally, Prothena stated in this presentation that the cardiac and renal response rates from its Phase 1/2 study "[c]ompares favorably to published historical response rates in patients previously-treated with plasma cell directed therapy."

30. On July 12, 2016, at the Cantor Fitzgerald Healthcare Conference, Defendants touted the new clinical trial results presented a week earlier. Defendant Kinney highlighted cardiac and renal response rates of 53% and 63% respectively, as well as the new neuropathy element of the study. Defendant Kinney underscored that, "now, with cardiac, renal and peripheral neuropathy improvement, we see three organ systems that are all moving in the same direction following intervention with NEOD001. So again, this gives us, I think, increased confidence in our ongoing pivotally designed studies, those being our Phase 2b PRONTO and our Phase 3 VITAL studies."

31. On August 2, 2016, Prothena filed its quarterly report for the second quarter 2016 with the SEC on Form 10-Q. The second quarter 2016 Form 10-Q reiterated the results of the Phase 1/2 study Prothena announced on July 5, 2016, reporting best response rates of 53% and 63% for cardiac and renal patients, respectively, which were "consistent with the interim analyst from the dose-escalation phase published February 2016 in the *Journal of Clinical Oncology*." Additionally, the Form 10-Q reported an 82% response rate for patients with peripheral neuropathy.

32. On September 12, 2016, at the Morgan Stanley Global Healthcare Conference,

Defendant Nguyen highlighted the "exciting" results of its ongoing Phase 1/2 trial and expressed confidence in the success of late-stage NEOD001 clinical trials. Defendant Nguyen stated, "we continue to see very consistent results from our dose escalation versus our expansion, and so that was very exciting for us. We saw greater than 50% response rates for cardiac and we saw greater than 60% response rates for kidney." Defendant Nguyen additionally highlighted the "very exciting" peripheral neuropathy results of the trial.

33. During the Morgan Stanley Global Healthcare Conference, Nguyen also represented to investors that the results of the Phase 1/2 trial had positive implications for NEOD001's late-stage VITAL and PRONTO studies due to positive data seen across three different organs. Defendant Nguyen stated:

> But in this case, we were actually showing improvements in eight patients, which was really exciting to us. And two of those eight patients actually completely resolved. So again, that was with the really exciting findings from the Phase I/II data that we shared in Sweden. But of course, all of that has to go back to what does it say about PRONTO and VITAL to us.
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> And what's important about the Phase I/II, just to draw the back -- build a bridge back to the PRONTO trial and also VITAL is that when we see improvements now in all three organs in these patients, we feel that with the Short-form 36, which is quality of life, and 6-minute walk, it is – those are integrated endpoints that account for the heart, the kidney, and also now peripheral neuropathy.

34. On November 2, 2016, Prothena filed its quarterly report for the third quarter 2016 with the SEC on Form 10-Q. The report reiterated the results of the Phase 1/2 study Prothena announced on July 5, 2016, reporting best response rates of 53% and 63% for cardiac and renal patients, respectively, which were "consistent with the interim analyst from the dose-escalation phase published February 2016 in the *Journal of Clinical Oncology*." Additionally, the Form 10-Q reported an 82% response rate for patients with peripheral neuropathy.

35. On December 4, 2016, Prothena presented its final Phase 1/2 trial results, concluding that the "best response rates are better than those reported for patients treated with plasma cell-directed therapies" and that "Encouraging results have now been observed across 3 organ systems." Prothena reported final best response figures of 53% and 64% for cardiac and

renal patients, respectively, and an 82% response rate for neuropathy patients. Also on December 4, 2016, the Company published an investor presentation titled "Organ Biomarker Responses in Patients With Light Chain Amyloidosis Treated With NEOD001 Are Independent of Previous Hematologic Responses." Through the presentation, the Company reassured the market that NEOD001 organ responses are not related to "Time since best or last HR," "Depth of best or last HR," "Time since last PCD therapy," and "Type of last PCD therapy."

36. On February 14, 2017, Prothena held a conference call with analysts and investors to discuss the Company's earnings for the fourth quarter and full year 2016. On that conference call, Defendant Kinney stated "Data from the study also demonstrated improvement in three organ systems: cardiac, renal, and peripheral nerve. Specifically, the results of the best-response analysis showed that 53%, or 19 of 36 of the cardiac-evaluable patients, demonstrated a cardiac response, and 64%, or 23 of the 36 renal-evaluable patients, demonstrated a renal response." Furthermore, Defendant Kinney highlighted the fact that the Phase 1/2 trial results were a good sign for success in future phases, stating: "[b]ased on these positive data from the Phase 1/2 study, we remain confident in the design and powering of our two ongoing clinical studies, the PRONTO and VITAL amyloidosis studies."

37. Defendant Kinney also stated during the February 14, 2017 conference call that the "response rates, achieved across three organ systems in our study, compared favorably to published historical response rates in patients previously treated with plasma cell-directed therapy." In order to assure investors that the Company's response rates were not the result of previous therapy, Defendant Kinney added, "a post-hoc subset analysis of the NEOD001 Phase 1/2 study results demonstrated that organ responses were not related to the time or depth of hematologic response achieved from previous plasma cell-directed therapy, nor were they related to the time or type of prior therapy."

38. On February 27, 2017, Prothena filed with the SEC its annual report on Form 10-K for the year ended December 31, 2016. In addition to reporting the final results of Prothena's Phase 1/2 study, reiterating the best response results of 53% and 64% for cardiac and renal patients, respectively, and an 82% response rate for neuropathy patients, Prothena continued to favorably

compare its findings to historical studies, stating in the 2016 Form 10-K:

> In a best response analysis of patients in the Phase 1/2 study who received NEOD001, 53% or 19 of 36 total cardiac-evaluable patients demonstrated a cardiac response, defined as more than 30% and 300 pg/mL decrease in levels of NT-proBNP. These cardiac best response rates compared favorably to cardiac response rates of 0% to 15% from available published historical data in patients previously treated with plasma cell directed therapy, and were consistent with the best response rate of 57%, or 8 of 14 cardiac-evaluable patients, reported in the interim analysis of the dose escalation phase (n=27) of the NEOD001 Phase 1/2 study published in the *Journal of Clinical Oncology* in February 2016.
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> In a best response analysis of patients in the Phase 1/2 study who received NEOD001, 64%, or 23 of 36 total renal-evaluable patients, demonstrated a renal response, defined as a 30% decrease in proteinuria in the absence of estimated glomerular filtration rate (eGFR) worsening. These renal best response rates compared favorably to renal response rates of 17% to 29% from published historical data in patients previously treated with plasma cell directed therapy, and were consistent with the best response rate of 60%, or 9 of 15 renal-evaluable patients, reported in the interim analysis of the dose-escalation phase (n=27) of the NEOD001 Phase 1/2 study published in the *Journal of Clinical Oncology* in February 2016.

39. On March 21, 2017, at the Oppenheimer Healthcare Conference, Defendant Kinney gave a presentation where he emphasized the results of Prothena's Phase 1/2 trial, specifically best response results of 53% and 64% for cardiac and renal-evaluable patients, respectively, and an 82% response rate for neuropathy patients. Additionally, Defendant Kinney discussed during this conference the relevance of the Phase 1/2 results to the Phase 2b PRONTO study, stating that PRONTO is "very similar to the Phase 1/2 study in as much as we're looking at patients that have previously had standard of care, but still have ongoing organ dysfunction."

40. On May 3, 2017, at the Deutsche Bank Health Care Conference, Defendant Kinney once again cited the results of the Phase 1/2 study, stating "in the Phase I/II study, over 50% of our patients who had received some chemotherapy targeting the plasma cell previously but hadn't had cardiac improvement showed cardiac improvement once they started on NEOD001." Defendant Kinney added that "[o]ver 60% of the renal patients that've been evaluated showed improvement in renal function. And almost -- I think it was 82% of our peripheral neuropathy patients showed some improvement by the definition of response for neuropathy."

41. On November 16, 2017, at Prothena's R&D Day, Defendant Noonberg touted the

results of Prothena's NEOD001 Phase 1/2 study, stating "in this first in-human study, we also observed organ responses in the 3 main organ systems I talked about earlier: cardiac, renal and the peripheral nervous system" adding that "the Phase I/II study gave us confidence then for PRONTO." The same day, the Company assured investors that its best response analysis was an appropriate framework for analyzing efficacy. Defendant Kinney told investors that "when you have patients at all different parts of their disease trajectory, then a best response analysis against the progressive background of disease is appropriate."

42. On January 10, 2018, at the JPMorgan Healthcare Conference, Prothena continued to reassure investors regarding its best response framework. In responding to an analyst question during the conference about presenting Phase 1/2 trial results over time, as opposed to best response results, Defendant Nguyen represented that such a figure "wouldn't be a good predictor. It just wouldn't." Additionally, Defendant Nguyen stated that best response criteria was appropriate because otherwise "you might miss a response."

43. On February 14, 2018, during a conference call with analysts and investors regarding Prothena's fourth quarter and full year 2017 earnings, Defendant Kinney again assured the market that the Company's best response analysis was appropriate, stating:

> Question – Kennen B. MacKay: Got you... And then just one more quick follow-up as it relates to doing some sort of historical comparisons throughout the trial landscape here. Can you talk a little bit about the sort of best response analysis for NT-proBNP that's been used sort of in a landscape fashion at a specific time point versus a best response over a period of time? And how that relates to the trials that you had run as well as some of the trials across the, again, historical landscape here and really, how we should think about sort of reconciling between these 2 different endpoints?
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> Answer – Gene G. Kinney: Yes, sure. So there -- so when people have looked at NT-proBNP response, they've done it multiple different ways. They've done it at various time points, 3 months, 6 months, 12 months. People have used best response. And I think what we can say is across all of those analyses, without any exception that I'm aware of, NT-proBNP response predicts survival following intervention.

44. The foregoing statements during the Class Period were materially false and misleading. First, Defendants deliberately withheld relevant trial data – *i.e.*, month-to-month data that showed patient response rates over a full study period – that cut against Defendants'

consistently positive statements. Instead, Prothena released only best response data selected to support Defendants' representations regarding NEOD001's efficacy. Second, Defendants made misleading comparisons of NEOD001's best response rates to prior studies that evaluated patient response after a specified period of time, and without consistently identifying those studies. Third, Defendants touted the results of its ongoing Phase 1/2 trial as a strong predicate for the launch and likely success of the Phase 2b PRONTO study and Phase 3 VITAL study, despite knowing from the full results of the Phase 1/2 study that NEOD001 was not effective, particularly when evaluated under customary standards.

VI. THE TRUTH BEGINS TO EMERGE

45. On June 29, 2017, the investment research firm Muddy Waters published a report questioning whether NEOD001 was effective and openly accused Prothena of presenting the early trial data in a misleading manner and having "selectively designed their trials to skew results." On this news, the price of Prothena stock fell 10% on intraday trading – the largest intraday decline in the preceding five months.

46. On November 8, 2017, Kerrisdale, another investment research firm, published a 27-page report that further exposed why Prothena's Phase 1/2 study results were misleading. The Kerrisdale report detailed why Prothena's best response measure "is a poor indicator of efficacy" and presents "blatant apples-to-oranges" comparison with prior studies, because Prothena compared its best response endpoint with published data that relies on a single fixed-duration measurement. On this news, the price of Prothena stock declined from $60.96 per share on November 7, 2017, to $56.24 per share on November 8, 2017, a drop of 7.8%.

47. On February 2, 2018, Prothena abruptly announced that its Chief Medical Officer, Defendant Noonberg, had resigned. As reported by *Seeking Alpha*, investors believed that "the exit of Sarah Noonberg, M.D., Ph.D., bodes ill for Phase 2 data on lead candidate NEOD001." On this news, the price of Prothena stock declined from $39.60 per share on February 2, 2018, to close at $32.14 per share when trading resumed on February 5, 2018, a drop of 19%.

48. On April 23, 2018, before the market opened, Prothena announced that it was ending all development of NEOD001 after data from its Phase 2b PRONTO trial showed that

NEOD001 failed to reach either its primary or secondary endpoints. With regards to the primary endpoint, NEOD001 patients exhibited a cardiac best response rate of only 39.4%, which was substantially below the 47.6% response rate of the placebo group. Accordingly, the independent data monitoring committee determined that it would be futile to continue the Phase 3 study, and recommended that it should be abandoned. On this news, the price of Prothena stock fell from $36.84 per share on April 20, 2018, the prior trading day, to close at $11.50 per share on April 23, 2018, a drop of 69%.

49. Investment analysts covering the Company expressed shock. Deutsche Bank called the trials results "disappointing and unexpected," Barclays stated that "[w]e wrongly thought the prior phase 1/2 data would predict success for the Phase 2b PRONTO Trial," and Evercore commented that "clearly [we] did not fully appreciate the significant risks." The market was also surprised that the unfavorable Phase 2b trial results led Prothena to end all NEOD001 development. For example, BTIG stated that "the discontinuation of the entire 001 program" was "unexpected," and RBC Capital Markets similarly underscored that "more surprising is the interim futility of the VITAL trial & full halt of NEOD001."

VII. LOSS CAUSATION

50. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to deceive the market. This artificially inflated the price of Prothena securities and operated as a fraud or deceit on the Class (as defined below). Later, when Defendants' prior misrepresentations and fraudulent conduct were disclosed to the market, the price of Prothena stock fell. As a result of their purchases of Prothena securities during the Class Period, Plaintiff and other members of the Class suffered harm.

VIII. CLASS ACTION ALLEGATIONS

51. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired the publicly traded common stock of Prothena during the Class Period (the "Class"). Excluded from the Class are Defendants and their families, directors, and officers of Prothena and their families and affiliates.

52. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Prothena has over 39 million shares of common stock outstanding, owned by hundreds or thousands of investors.

53. There is a well-defined community 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 which predominate over questions which may affect individual Class members include:

(a) Whether Defendants violated the Exchange Act;

(b) Whether Defendants omitted and/or misrepresented material facts;

(c) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether Defendants knew or recklessly disregarded that their statements and/or omissions were false and misleading;

(e) Whether the price of Prothena common stock was artificially inflated;

(f) Whether Defendants' conduct caused the members of the Class to sustain damages; and

(g) The extent of damage sustained by Class members and the appropriate measure of damages.

54. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

55. Plaintiff will adequately protect the interests of the Class and has retained counsel experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

56. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

IX. INAPPLICABILITY OF STATUTORY SAFE HARBOR

57. Prothena's "Safe Harbor" warnings accompanying its forward-looking statements

issued during the Class Period were ineffective to shield those statements from liability.

58. Defendants are also liable for any false or misleading forward-looking statements pleaded herein because, at the time each such statement was made, the speaker knew the statement was false or misleading and the statement was authorized and/or approved by an executive officer of Prothena who knew that the statement was false. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to, or stated to be dependent on, those historic or present tense statements when made.

X. PRESUMPTION OF RELIANCE

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

(a) Prothena stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Prothena filed periodic public reports with the SEC and NASDAQ;

(c) Prothena regularly and publicly communicated with investors via established market 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 communications with the financial press and other similar reporting services; and

(d) Prothena was followed by several securities analysts employed by major brokerage firm(s) who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace.

60. As a result of the foregoing, the market for Prothena common stock promptly digested current information regarding Prothena from all publicly available sources and reflected

such information in the price of Prothena common stock. Under these circumstances, all purchasers of Prothena common stock during the Class Period suffered similar injury through their purchase of Prothena common stock at artificially inflated prices and the presumption of reliance applies.

61. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class' claims are grounded on Defendants' material omissions.

COUNT I

For Violations Of Section 10(b) Of The Exchange Act And Rule 10b-5 Against All Defendants

62. Plaintiff repeats, incorporates and realleges each and every allegation contained above as if fully set forth herein.

63. During the Class Period, Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Prothena common stock at artificially inflated prices.

64. Defendants (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 not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Prothena common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

65. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the Company's financial well-being, operations, and prospects.

66. During the Class Period, Defendants made the false statements specified above, which they knew or recklessly disregarded to be false and misleading in that they contained

misrepresentations and 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.

67. Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or recklessly disregarded the true facts that were available to them. Defendants engaged in this misconduct to conceal Prothena's true condition from the investing public and to support the artificially inflated prices of the Company's common stock.

68. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Prothena common stock. Plaintiff and the Class would not have purchased the Company's common stock at the prices they paid, or at all, had they been aware that the market prices for Prothena common stock had been artificially inflated by Defendants' fraudulent course of conduct.

69. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases of the Company's common stock during the Class Period.

70. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT II

For Violations Of Section 20(a) Of The Exchange Act Against The Individual Defendants

71. Plaintiff repeats, incorporates, and realleges each and every allegation set forth above as if fully set forth herein.

72. The Individual Defendants acted as controlling persons of Prothena within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, participation in and/or awareness of the Company's operations, direct involvement in the day-to-day operations of the Company, and/or intimate knowledge of the Company's actual performance, and their power to control public statements about Prothena, the Individual Defendants had the power and ability to control the actions of Prothena and its employees. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

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XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees;

D. Awarding such equitable/injunctive or other further relief as the Court may deem just and proper.

XII. JURY DEMAND

Plaintiff demands a trial by jury.

Dated: May