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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

MYO THANT, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

RAIN ONCOLOGY INC., AVANISH VELLANKI, RICHARD BRYCE, FRANKLIN BERGER, AARON DAVIS, GORJAN HRUSTANOVIC, TRAN NGUYEN, PETER RADOVICH, and STEFANI A. WOLFF,

Defendants.

Case No. 5:23-cv-03518-EJD

AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

CLASS ACTION

Demand for Jury Trial

Lead Plaintiff Dr. Myo Thant and additional named plaintiff Branden Schenkhuizen (collectively "Plaintiffs") allege the following upon information and belief, except as to those allegations concerning themselves, which are alleged upon personal knowledge. Plaintiffs' information and belief is based on the investigation of their undersigned counsel, which included, among other things, review and analysis of: (a) public statements made by or on behalf of Rain Oncology Inc. f/k/a Rain Therapeutics Inc. ("Rain" or the "Company"), including public filings with the U.S. Securities and Exchange Commission ("SEC"); (b) press releases; (c) reports of securities and financial analysts; (d) news articles; (e) industry reports; and (f) interviews with former employees of Rain. Plaintiffs believe that substantial additional

evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE CLAIM

1. Plaintiffs bring this action pursuant to of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §78a, et seq., and Rule 10b-5 promulgated thereunder, on behalf of himself and all persons similarly situated who purchased Rain common stock between April 23, 2021 to May 19, 2023, inclusive (the "Class Period") (the "Exchange Act Claims"). Plaintiffs also assert claims under Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act"), 15 U.S.C. §§ 77k and 77o (the "Securities Act Claims").

2. Rain introduced itself to investors during its initial public offering as a "clinical-stage precision oncology company" on the verge of launching a "pivotal Phase 3 trial" for a liposarcoma drug with a potential market value of $1 billion. Integral to Rain's pitch was the claim that the Phase 3 trial had been "de-risked" based on trial data collected during a previous Phase 1 trial. According to Rain and its senior executive officers, the Phase 1 trial data was so strong that it supported the Company's decision to advance directly to a Phase 3 trial and completely skip Phase 2. This maneuver, which is referred to as "Phase 2 Bypass," is appropriate in only limited, narrow circumstances. Those circumstances were not present in this case. Unfortunately, investors who bought in on the hype found out too late and only after they lost nearly everything.

3. Clinical trials in the United States are typically conducted in three phases. Phase 1 is performed to test the safety profile of a drug and identify tolerable doses. If the drug appears to be reasonably safe, the doses identified in Phase 1 are then used in a Phase 2 trial across a larger population. Phase 3 is then conducted across an even greater number of participants to obtain enough safety and efficacy information to support a "New Drug Application" with the U.S. Food & Drug Administration. Only upon approval of a New Drug Application can a drug company proceed to commercialize the drug and generate revenue from sales.

4. Although not commonly done, a drug company can skip Phase 2 in the clinical trial process (*i.e.*, Phase 2 Bypass) where the drug's mechanism of action and safety profile are well characterized. A drug's mechanism of action refers to the specific biochemical interaction through

which a drug substance produces its pharmacological effect, *e.g.*, the specific molecular targets to which a drug binds or how the drug works from a biochemical point of view. The safety profile of a drug refers to the frequency of adverse effects that are treatment emergent or how likely a drug is to cause its user to suffer adverse side effects.

5. The drug at issue in this case is milademetan. Milademetan was a small molecule, oral inhibitor of mouse double minute 2 ("MDM2"). MDM2 is a protein in humans that can accelerate tumor growth if left unsuppressed. MDM2 inhibitors (which is a category of drugs that included milademetan) have historically been associated with severe hematologic events. Although MDM2 inhibitors have been studied for almost two decades, none has progressed past early-phase clinical trials in solid-tumor patients due to the fact that they cause myelosuppression (*i.e.*, a decrease in bone marrow activity that results in reduced production of blood cells).

6. A Japanese corporation named Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), initially developed milademetan and conducted its Phase 1 clinical trial. The Phase 1 trial was a "first-in-human" trial, meaning that it was the first time milademetan was ever given to humans. The Phase 1 trial data demonstrated that milademetan administered at a particular dose resulted in a 3-4x improvement in patients with well-differentiated/de-differentiated ("WD/DD") liposarcoma ("LPS") over general standard of care treatment. These results, however, were based on a subset of data from just 16 patients within the study or roughly 15% of the overall trial.

7. In September 2020, Rain acquired a license to develop and potentially sell milademetan from Daiichi Sankyo. Defendants told investors during Rain's initial public offering and throughout the Class Period that Daiichi Sankyo's Phase 1 trial data supported skipping Phase 2 and proceeding directly to a Phase 3 trial. Defendants made this claim even though milademetan did not meet the criteria for Phase 2 Bypass and in spite of the fact that Daiichi Sankyo's clinical trial plan called for a Phase 2 trial.

8. The risks associated with Rain's Phase 2 Bypass were severe and well-above those that reasonable investors expected to assume when investing in the stock. Contrary to Defendants' public representations, the Phase 1 data did not sufficiently identify the correct dosage for milademetan. Had Rain conducted the Phase 2 trial, this would have come to light and could have

been corrected. However, Defendants decided to roll the dice and engage in a reckless gamble with the money they raised from their public investors. If the Phase 3 trial results proved favorable, then Rain would have successfully saved hundreds of millions of dollars that the Company otherwise would have had to spend conducting a lengthy Phase 2 trial. Moreover, by skipping the Phase 2 trial, Rain increased the odds of making it first to market, thereby ensuring its superiority status against the competition.

9. Defendants' intentions in this regard are unmistakable. The SEC repeatedly admonished Defendants and, in particular, Rain's Chief Executive Officer, Avanish Vellanki, for making unsupported statements in the Company's registration statement and prospectus. As soon as the initial public offering was done, Vellanki and his fellow senior executives, including the Company's Executive Vice President and Chief Medical Officer, Richard Bryce, resorted to making the same false and baseless claims they were told not to make. Above all, despite the acute risks associated with the Phase 2 Bypass, Defendants repeatedly referred to their rapid commencement of the Phase 3 study as a boon to the Company and its overall prospects.

10. The truth finally emerged when, on May 22, 2023, Rain announced that its Phase 3 trial failed due to a lack of efficacy and elevated levels of adverse safety events. Analysts reported on the results, noting the risks of proceeding directly to a Phase 3 trial from Phase 1. The analysts also noted the increased level of Grade 3/4 hematologic adverse events, which suggested that the dosing schedule had not been properly optimized during the Phase 1 trial. Analysts also noted that Rain's Chief Scientific Officer, Robert C. Doebele, acknowledged during a conference call earlier in the day that the 260 mg dose was too high. In response to the news, Rain's stock price declined from $9.93 per share on May 19, 2023 to $1.22 per share on May 22, 2023.

11. During the Class Period, Plaintiffs and other similarly situated investors bought Rain securities at artificially inflated prices due to Defendants' false and/or materially misleading statements. When the truth concerning Rain's clinical trial risks emerged, Rain's stock price decreased resulting in significant losses to investors. This action seeks to compensate those investors and recover the damages they sustained because of Defendants' actions and statements.

JURISDICTION AND VENUE

12. The Exchange Act Claims asserted herein arise under and pursuant to 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). The Securities Act Claims arise under and pursuant to Sections 11 and 15 of the Securities Act, 15 U.S.C. §§ 77k and 77o, respectively.

13. This Court has subject matter jurisdiction over this action under Section 27 of the Exchange Act (15 U.S.C. §78aa), Section 22 of the Securities Act (15 U.S.C. § 77v), and 28 U.S.C. § 1331.

14. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly and/or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

15. Venue is proper in this District pursuant to Section 27 of the Exchange Act, Section 22 of the Securities Act, and 28 U.S.C. § 1391(b) because certain of the acts alleged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in this District.

PARTIES

16. Lead Plaintiff Dr. Myo Thant purchased Rain securities at artificially inflated prices during the Class Period and was damaged upon the revelation of Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Rain is incorporated herein by reference. *See* ECF No. 19-2.

17. Additional named plaintiff Branden Schenkhuizen purchased Rain securities pursuant and/or traceable to the Company's registration statement and prospectus filed in conjunction with the initial public offering, and was damaged thereby. Mr. Schenkhuizen's certification evidencing his transaction(s) in Rain is filed herewith.

18. Defendant Rain was founded in 2017 and is incorporated in the State of Delaware. Its principal executive offices are located at 8000 Jarvis Avenue, Suite 204, in Newark, California 94560. During the Class Period, Rain's securities traded in an efficient market on the Nasdaq under

the symbol "RAIN". Rain is presently set to be acquired by Pathos AI, a biopharmaceutical company focused on developing artificial intelligence-powered pathology tools, via a tender offer.

19. Defendant Avanish Vellanki ("Vellanki") is the Company's Chairman and Chief Executive Officer. Vellanki has 20 years of experience across the healthcare and investment banking sectors. After his start at Bear, Stearns & Co. in 2004 in equity research, Vellanki transitioned to Global Healthcare Investment Banking at Citigroup where he focused on large-cap global biopharmaceutical companies. He subsequently moved to the healthcare industry, joining Proteolix in 2009 prior to its acquisition by Onyx Pharmaceuticals, where he helped develop carfilzomib (Kyprolis(R)) for patients with multiple myeloma. Prior to founding Rain, Avanish was senior vice president and chief business officer at Aptose Biosciences.

20. Defendant Richard Bryce, M.B.Ch.B. ("Bryce"), is the Company's Executive Vice President and Chief Medical Officer. Prior to joining Rain in April 2021, Dr. Bryce served as Chief Medical and Scientific Officer at Puma Biotechnology, Inc., a biopharmaceutical company, from June 2012 to April 2021.[1] Prior to that, he had served as the Executive Vice President of Medical Affairs at clinical research organizations Ergomed PLC and ICON plc (as Senior Director of Medical Affairs and Oncology). He also served as Senior Medical Director of Clinical Science at biopharmaceutical company Onyx Pharmaceuticals, Inc. Earlier in his career, Dr. Bryce held a variety of senior clinical and medical roles at F. Hoffmann-La Roche AG (OTCMKTS: RHHBY), a pharmaceutical company, ILEX Oncology, Inc., a biopharmaceutical company, Scotia Pharmaceuticals Ltd., a pharmaceutical company, and Servier Laboratories, a pharmaceutical company.

21. Defendants Vellanki and Bryce are collectively referred to herein as the "Individual Defendants."

22. Defendants Franklin Berger, Aaron Davis, Gorjan Hrustanovic, Tran Nguyen, Peter Radovich, Stefani A. Wolff were members of Rain's Board of Directors when Rain filed its

[1] On February 4, 2019, a federal jury found Puma Biotechnology and certain of its senior officers liable for violating the federal securities laws. *See Hsu v. Puma Biotechnologies, Inc., et al*., No. 8:15-cv-00865-DOC-SHK, ECF No. 718 (Verdict Form).

registration statement and prospectus in conjunction with the Company's initial public offering. Collectively, these defendants are referred to as the "Director Defendants."

23. Each of the Individual Defendants and Director Defendants:

(a) directly participated in the management of Rain;

(b) was directly involved in the day-to-day operations of Rain at the highest levels;

(c) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(d) was directly or indirectly involved in the oversight or implementation of Rain's business and/or finances, medical, or scientific research;

(e) was aware of or deliberately recklessly disregarded the fact that the false and misleading statements were being issued concerning Rain; and/or

(f) approved or ratified these statements in violation of the federal securities laws.

24. Because of the Individual and Director Defendants' positions within Rain, they had access to undisclosed information about the true nature of and risks inherent in the Company's Phase 3 MANTRA study.

25. As officers of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the federal securities laws of the United States, the Individual and Director Defendants each had a duty to disseminate prompt, accurate and truthful information with respect to the Company's clinical trial plan for milademetan and to correct any previously-issued statements that had become materially misleading or untrue.

26. The Individual and Director Defendants, because of their positions with Rain, possessed the power and authority to control the contents of Rain's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual and Director Defendant 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 these 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. The Individual and Director Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

27. Each of the Individual Defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Rain's securities by disseminating materially false and misleading statements and/or concealing material adverse facts. This scheme caused Plaintiffs and other shareholders to purchase Rain's securities at artificially inflated prices. Similarly, the Director Defendants are liable for disseminating materially false and/or untrue statements, or failing to disclose material adverse information, due to their negligence in preparing Rain's registration statement and prospectus for the Company's initial public offering.

SUBSTANTIVE ALLEGATIONS

A. *Phase 2 Bypass.*

28. Federal law requires pharmaceutical companies to obtain permission from the FDA before marketing a drug to the public and, in turn, generating revenue from sales. To obtain permission, a company (or sponsor) must demonstrate that the drug is safe, effective, and that its benefits outweigh its risks. This is typically done through clinical trials and the submission of a New Drug Application ("NDA"). All drugs currently marketed within the United States were, at some point, the subject of an approved NDA.

29. A properly submitted NDA provides the FDA with all pertinent information about the drug, including data and statistical analyses sufficient to determine whether: (1) the drug is safe and provides the benefits it purports to; (2) the benefits of the drug outweigh its risks; (3) the drug's proposed labeling is appropriate and what it should contain; and (4) the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. Although safety and efficacy are

particularly important in the FDA's assessment, each of these issues is independently critical to the agency's ultimate approval decision.

30. In order to meet these standards, drug developers typically subject a drug candidate to a series of clinical trials designed to accumulate the data required to submit a successful NDA. Phase 1 clinical trials typically evaluate an investigational drug's safety and dosage tolerance. Phase 2 clinical trials: (1) usually involve larger patient populations; (2) evaluate dosage tolerance and appropriate dosage; (3) identify possible short-term adverse effects and safety risks; and (4) provide a preliminary evaluation of the efficacy of the drug for specific indications. Finally, Phase 3 clinical trials test for efficacy and safety in an even further expanded patient population. Phase 3 trials also usually involve comparison with placebos and are intended to establish the overall risk-benefit profile of the product and provide an adequate basis for physician labeling.

31. "Phase 2 Bypass" is a process whereby a drug developer or sponsor skips the Phase 2 clinical trial and advances from Phase 1 directly to Phase 3. Phase 2 Bypass is only done in limited, narrow circumstances where the drug's mechanism of action and safety profile are well characterized. A drug's mechanism of action refers to the specific biochemical interaction through which a drug substance produces its pharmacological effect, *e.g.*, the specific molecular targets to which a drug binds or how the drug works from a biochemical point of view. The safety profile of a drug refers to the frequency of adverse effects that are treatment emergent or how likely a drug is to cause its user to suffer adverse side effects.

32. Absent these criteria (*i.e.*, a well-characterized mechanism of action and safety profile), Phase 2 Bypass is not done due to the acute risks it presents. These risks include exposure to unproven and potentially dangerous therapies and wasted commitment of resources in Phase 3 trials. In addition, a Phase 2 Bypass outside of accepted circumstances can result in a lost opportunity to refine dosing schedules for the Phase 3 trial and the inability to establish sufficient evidence showing the drug's clinical benefit beyond existing standards of care.

33. Medical and academic research widely confirms that Phase 2 Bypass should not be used except when the drug's mechanism of action and safety profile are well characterized. For example, the following peer reviewed published articles and research guidelines stand for the

premise that Phase 2 Bypass when used outside of customary practice and ordinary standards of care materially reduces the chances of obtaining successful Phase 3 data and results in significantly worse survival and safety outcomes:

a) Balasubramanian A, et al., Inefficiencies in phase II to phase III transition impeding successful drug development in glioblastoma. Neurooncology Adv 2020;

b) Gormley NJ, et al, Immunotherapy combinations in multiple myeloma – known unknowns. New Engl J Med 2018;

c) Addeo A, et al., Association of industry and academic sponsorship with negative phase 3 oncology trials and reported outcomes on participant survival: a pooled analysis. JAMA Netw Open 2019;

d) Chan JK, et al., Analysis of phase II studies on targeted agents and subsequent phase III trials: what are the predictors for success? JCO 2008;

e) Liang F, Wu Z, Mo M, Zhou C, Shen J, Wang Z, et al. Comparison of treatment effect from randomised controlled phase II trials and subsequent phase III trials using identical regimens in the same treatment setting. Eur J Cancer 2019;

f) Hegge SJ, Thunecke ME, Krings M, Ruedin L, Mueller JS, von Buenau P. Predicting success of phase III trials in oncology. Oncology 2020;

g) Jardim DL, Groves ES, Breitfeld PP, Kurzrock R. Factors associated with failure of oncology drugs in late-stage clinical development: a systematic review. Cancer Treat Rev 2017;

h) Tempero M, et al., Ibrutinib in combination with nab-paclitaxel and gemcitabine for first-line treatment of patients with metastatic pancreatic adenocarcinoma: phase III RESOLVE study. Ann Oncol 2021;

i) Baselga J, et al. Buparlisib plus fulvestrant versus placebo plus fulvestrant in postmenopausal, hormone receptor-positive, HER2-negative, advanced

breast cancer (BELLE-2): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Oncol 2017;

j) Booth CM, et al., Design and conduct of phase II studies of targeted anticancer therapy: recommendations from the task force on methodology for the development of innovative cancer therapies (MDICT). Eur J Cancer 2008; and

k) Brown S, et al., A Practical Guide to Designing Phase II Trials in Oncology: Brown/A Practical 2014.

34. Notwithstanding the foregoing, a reckless drug developer or sponsor could be motivated to disregard the foregoing in hopes of saving time and money. Average costs for cancer drug trials are $4.5 million for Phase 1, $11.2 million for Phase 2, and $22.1 million for Phase 3, according to research reports. Thus, Phase 2 Bypass when used outside of customary practice and ordinary standards of care is a gamble that, at best, allows a company to expedite the clinical trial process at a fraction of the cost or, at worst, ends in a failed Phase 3 trial leaving the Company with no funds and no viable way to obtain FDA approval.

B. *The Phase 1 Trial for Milademetan.*

35. Daiichi Sankyo conducted milademetan's Phase 1 clinical trial. The trial was officially titled "A Phase 1 Multiple Ascending Dose Study of Milademetan in Subjects With Advanced Solid Tumors or Lymphomas" but Daiichi Sankyo referred to it as "U101".

36. U101 took place between July 2013 and October 2020. It was a single-arm, open-label study designed to test milademetan in patients with solid tumors or lymphomas. When initiated in July 2013, the study represented the first clinical trial in which milademetan was administered to humans, *i.e.*, a first-in-human study. One of U101's primary objectives was to identify a recommended Phase 2 dose, according to Daiichi Sankyo's study plan.

37. Daiichi Sankyo conducted U101 at five test sites within the United States. Initially, U101 consisted of two parts: Part 1 was a dose-escalation part aimed at identifying the maximum tolerable dose; and Part 2 was a dose-expansion part to test the safety and tolerability of potential doses. Part 2 was ultimately abandoned after Daiichi Sankyo determined it could not meet the

objectives under its dosing schedule because the dose identified as effective was not tolerable, *i.e.*, the dose was too toxic for study participants. U101's study protocol identified various endpoints to measure the efficacy of milademetan. These efficacy endpoints included objective response rate, time to response, response duration, and progression-free survival.

38. During the trial, milademetan was initially given orally once daily on a 28-day cycle at a starting dose of 15 mg. Due to excessive toxicity, Daiichi Sankyo explored intermittent dosing schedules and ultimately identified a recommended dose for further evaluation (*i.e.*, the recommended Phase 2 dose) of 260 mg once daily on days 1 to 3 and 15 to 17 every 28 days. This dose was not part of the initial study protocol but instead identified while U101 was underway. Only 16 study participants with dedifferentiated liposarcoma received this dose in the U101 trial. This subgroup of study participants represented 15% of U101's overall population. The subgroup demonstrated a median progression-free survival of 7.4 months (compared to 2.1 months under current standard of care treatment).

C. *Rain's Phase 3 Gamble.*

39. Rain went public in April 2021. Within its initial public offering documents, Rain prominently featured the Company's licensing deal with Daiichi Sankyo for the exclusive worldwide rights to develop and commercialize milademetan. In pertinent part, Rain's prospectus for the initial public offering described the licensing agreement as follows:

> On September 2, 2020, we entered into a license agreement with Daiichi Sankyo Company, Limited (Daiichi Sankyo), a Japanese corporation (the Daiichi Sankyo License Agreement). Pursuant to the Daiichi Sankyo License Agreement, we obtained a worldwide, sublicensable (through multiple tiers), royalty-bearing, exclusive right and license under Daiichi Sankyo's know-how and seven families of patents and patent applications to make, have made, use, import and export milademetan (RAIN-32) (the Licensed Compound) for all human prophylactic or therapeutic uses that derive therapeutic effect by binding to MDM2 for the prevention and treatment of any indication for the purpose of making, having made, using, offering for sale, selling, marketing, distributing, importing, and exporting products containing milademetan as an active pharmaceutical ingredient (the Products).

40. Rain's prospectus also described Daiichi Sankyo's Phase 1 trial for milademetan. It explained that the "objective of the Phase 1 trial was to identify a maximum tolerated dose" and that over the course of the trial, it developed an "intermittent dosing schedule" that would be used

in future trials. The intermittent dosing schedule (referred to as "Schedule D") was a dose of 260 mg for three days every 14 days, as described above (*i.e.*, 260 mg once daily on days 1 to 3 and 15 to 17 every 28 days). Rain told investors that "patients treated on Schedule D at a dose of 260 mg (MTD) had a mPFS of 7.4 months, which was longer than the reported mPFS of 2.2 months for trabectedin and 2.0 months for eribulin in WD/DD LPS patients." In other words, Rain represented "[d]ata from WD/DD LPS patients in the Phase 1 clinical trial demonstrated median progression-free survival (mPFS) approximately three to four times greater than the current standards of care (SOC), trabectedin or eribulin."

41. When describing the Phase 1 trial data, Rain's prospectus did not disclose Daiichi Sankyo's intent to conduct a two-part trial, where the first part would be to identify a dose and the second part would then test that dose across an expanded population, or that the results of the Phase 1 trial would be used to develop and conduct a Phase 2 trial. Instead, Rain stated repeatedly that the Phase 1 trial results supported "rapidly" advancing directly to a "pivotal Phase 3 trial in WD/DD LPS patients."

42. Analysts from top-tier investment banks issued "buy" and "overweight" ratings based on Rain's representations. These analysts echoed Rain's statements about the Phase 1 trial data and how it significantly "de-risked" miladametan and supported the Company's plans to advance directly to a Phase 3 trial.

43. Rain used its initial public offering to raise $121.9 million in net proceeds from retail investors. According to its prospectus, Rain intended to use approximately $60 million of the cash to fund clinical trials, including its "pivotal Phase 3 trial" for miladametan. Rain told investors in its prospectus that the cash raised from the initial public offering was sufficient to fund operations through 2024.

D. *The MANTRA Trial.*

44. On July 20, 2021, Rain commenced its Phase 3 trial for miladametan. Rain referred to the trial as the "MANTRA" trial and described it as follows:

> The MANTRA trial, a randomized, multicenter, open-label, Phase 3 registrational study, is designed to evaluate the safety and efficacy of RAIN-32 compared to trabectedin, a current standard of care, in patients with unresectable or metastatic

> DD LPS with or without a well-differentiated (WD) LPS component that has progressed on one or more prior systemic therapies, including at least one anthracycline-based therapy. Approximately 160 patients are expected to be randomized in a 1:1 ratio to receive milademetan or trabectedin. The primary objective of the trial is to compare progression-free survival (PFS) by blinded independent review between the milademetan treatment arm and the trabectedin control arm. Secondary endpoints include overall survival, PFS by investigator assessment, objective response rate, duration of response, disease control rate, safety and patient reported outcomes.

45. Analysts reported that Rain commenced the Phase 3 trial in line with its prior guidance, *i.e.*, the second half of 2021 or 2H21. Analysts also reiterated that the Phase 3 trial was clinically de-risked, given Rain's statements about the Phase 1 trial data. Analysts reconfirmed their "overweight" and "buy" ratings for Rain.

46. On September 20, 2021, while Rain's Phase 3 trial was ongoing, Daiichi Sankyo published results from a separate clinical trial testing milademetan in patients with intimal sarcoma (*i.e.*, tumors that arise in the pulmonary artery). The trial results reported unusually high rates of hematologic toxicities, including Grade 3 events of thrombocytopenia, neutropenia, white blood cell decreases, and anemia. The results also included a 20% objective response rate. The study participants received 260 mg doses of milademetan.

47. On May 22, 2023, Rain announced topline results for its Phase 3 trial, *i.e.*, the MANTRA trial. The trial did not meet the primary endpoint of progression free survival. In pertinent part, Rain described the results as follows:

> The median PFS for milademetan was 3.6 months vs 2.2 months for trabectedin, with a hazard ratio of 0.89, p=0.53. The most common treatment emergent adverse events (TEAEs) in the milademetan arm included nausea, thrombocytopenia, anemia, vomiting and neutropenia. The most common Grade 3/4 TEAEs were thrombocytopenia (39.5%), neutropenia (25.5%) and anemia (18.6%). Dose reductions in the milademetan arm were 44.2% vs 29.1% in the trabectedin arm. Discontinuation in the milademetan arm due to AEs were 11.6% vs 19.0% for trabectedin. Based upon these topline data, Rain does not expect to pursue further development of milademetan in DD LPS.
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> Phase 3 MANTRA Topline Data Results:

- The median PFS was 3.6 months with milademetan versus 2.2 months for trabectedin, with a hazard ratio of 0.89 (95% CI [0.61 to 1.29]; p=0.53) based on 115 events
- Most common TEAEs in the milademetan arm included nausea, thrombocytopenia, anemia, vomiting and neutropenia
- The most common Grade 3/4 TEAEs in the milademetan arm were thrombocytopenia (39.5%), neutropenia (25.5%) and anemia (18.6%)
- Dose reductions in the milademetan arm were 44.2% vs 29.1% in the trabectedin arm
- Discontinuations in the milademetan arm due to AEs were 11.6% vs 19.0% for trabectedin
- Treatment emergent SAEs in the milademetan arm were 36.0% vs 48.1% in the trabectedin arm

48. Analysts from several top-tier investment banks downgraded Rain in response to the news. In their reports, the analysts noted the risks of proceeding directly to a Phase 3 trial from Phase 1. They also noted that the Phase 3 trial results included more Grade 3/4 hematologic adverse events (*i.e.*, thrombocytopenia, anemia, and neutropenia) than anticipated. According to the analysts, the elevated level of adverse events suggested that the dosing schedule had not been properly optimized during the Phase 1 trial. Analysts also noted that Rain's Chief Scientific Officer, Robert C. Doebele, acknowledged during a conference call earlier in the day that the 260 mg dose was too high.

49. Rain abandoned its clinical trial plan for milademetan after the Phase 3 trial failed. On May 22, 2023, contemporaneously with the announcements of the Phase 3 trial results, Rain confirmed that it was no longer pursuing any line of therapy involving milademetan for the treatment of DD LPS. Given that DD LPS was the highest probability indication for an MDM2 inhibitor (such as milademetan), analysts immediately lowered their models for Rain while investors likewise decided to exit their positions in the stock. In the span of just one day, Rain's stock price declined from $9.93 per share on May 19, 2023 to $1.22 per share on May 22, 2023.

50. On May 28, 2023, Rain suspended ongoing clinical development of milademetan. The Company also decided to wind down research and development activities, implement a substantial reduction in force, and initiate a review of strategic alternatives. Rain's Board of Directors also instructed management to identify potential financial advisors to assist the Company in connection with its exploration of strategic alternatives.

51. On May 30, 2023, Rain announced plans to suspend further development of milademetan, including suspension of enrollment in the ongoing Phase 2 MANTRA-2 basket trial and the termination of plans for its Phase 1/2 MANTRA-4 combination trial, as well as a reduction in headcount of approximately 65%, and a plan to evaluate alternatives to enhance its pipeline through precision oncology program acquisitions or other transactions.

52. On August 10, 2023, Rain reported its financial earnings for the second quarter of fiscal 2023. In pertinent part, the Company announced it had decided to discontinue the entire development program for milademetan, including its other ongoing MANTRA studies. Rain also announced it had decided to focus on "cost-saving measures, including a reduction in force," and was actively looking for new opportunities to license or acquire clinical-stage programs and technologies.

53. On October 17, 2023, Rain entered into a non-disclosure agreement with Pathos AI, a biopharmaceutical company focused on developing artificial intelligence-powered pathology tools. The purpose of the agreement was to allow both companies to share information with one another to negotiate a merger or acquisition.

54. On November 16, 2023, Rain and Pathos AI executed a proposal whereby Pathos AI would acquire Rain through a tender offer.

55. On December 13, 2023, Rain announced the acquisition by Pathos AI. According to the announcement, Pathos AI will acquire Rain for $1.16 per share plus contingent value rights equaling approximately $0.17 per share based on the deal closing and milademetan's first patient dosing within five years. Rain shareholders presently have until January 25, 2024 to tender their shares under the terms of the acquisition agreement.

E. *Extreme Departure from Standards of Ordinary Care.*

56. Rain contravened customary practices, industry standards, and widely-accepted academic literature by abandoning Daiichi Sankyo's clinical trial plans and advancing milademetan directly from Phase 1 to Phase 3, *i.e.*, Phase 2 Bypass.

57. Milademetan did not qualify for Phase 2 Bypass. Its mechanism of action and safety profile were not well characterized. Milademetan was a small molecule, oral inhibitor of mouse

double minute 2 (previously defined as "MDM2"). MDM2 is a protein in humans that can accelerate tumor growth if left unsuppressed. MDM2 inhibitors (which is a category of drugs that includes milademetan) have historically been associated with severe hematologic events. Although MDM2 inhibitors have been studied for almost two decades, none has progressed past early-phase clinical trials in solid-tumor patients due to the fact that they cause myelosuppression (*i.e.*, a decrease in bone marrow activity that results in reduced production of blood cells).

58. Milademetan, as an MDM2 inhibitor, had not received marketing authorization from any regulatory agency and, as such, the drug had no clinical practice history. In fact, Daiichi Sankyo's Phase 1 trial was a "first-in-human" study, meaning that it was the first time ever that milademetan was administered to humans. According to Daiichi Sankyo's study protocol, the goal of the Phase 1 trial was to establish a recommended Phase 2 dose, thereby confirming that a Phase 2 dose had been and was intended to follow the Phase 1 trial.

59. The need for a Phase 2 trial was especially prevalent given that Daiichi Sankyo was unable to complete Part 2 of the Phase 1 trial, as initially anticipated. Part 2 of the Phase 1 trial was supposed to serve as a dose expansion part in which the recommended dose would be administered to an expanded population of study participants. Instead, Daiichi Sankyo identified the recommended Phase 2 dose (*i.e.*, 260 mg once daily on days 1 to 3 and 15 to 17 every 28 days) during the Phase 1 as opposed to being part of the study protocol from the outset, which undermined the reliability of the results. In total, the Phase 1 trial data that Rain supposedly relied upon when advancing directly to Phase 3 consisted of only 16 patients, which amounted to only 15% of the overall Phase 1 trial participants.

60. Former Employee 1 ("FE1") was a Senior Director, Program Management, at Rain from December 2020 to December 2021. FE1 was responsible for the coordination of drug development, working with different teams from different departments within the Company. FE1's duties included tracking the development progress of a drug and providing senior leadership, including Vellanki and Bryce, with updates. FE1 reported to Vellanki.

61. FE1 confirmed that within the field of oncology drug development, Phase 2 trials are generally necessary to "dial down" on the specific dosing level of the drug candidate. Phase 2

trials are used to identify a dose or doses that are then tested in a Phase 3 trial, according to FE1. FE1 explained that milademetan, in particular, was very difficult and challenging in terms of identifying a dose because it was not suitable for daily use due to the biology of the molecule at issue and the toxicity it created. Milademetan necessitated atypical dosing.

62. FE1 confirmed further that the Phase 1 trial conducted by Daiichi Sankyo did not "dial in" the dosing for milademetan. In fact, FE1 confirmed that Daiichi Sankyo's Phase 1 study recommended a dosing schedule for a Phase 2 trial as opposed to a Phase 3 trial. Daiichi Sankyo's trial results indicated a "recommended Phase 2 dose," which means that the dose is then tested in a Phase 2 trial, according to FE1. FE1 explained that drug developers generally do not advance directly to Phase 3 trials at this point because the dataset, *i.e.*, the patient population, for dosing schedules is usually too small. FE1 explained further that if drug developers or sponsors proceed straight to Phase 3 with a "recommended Phase 2 dose" from a Phase 1 trial, the dosing schedule might not work and the study may need to be redone. A Phase 2 trial allows the sponsor to test the recommended Phase 2 dose accordingly and then, if the data supports it, commence a Phase 3 trial to confirm the results.

63. FE1 explained that in the case of Rain and milademetan, the Company should advancing directly from Phase 1 to Phase 3 was a big jump and pretty aggressive given the limited amount of patient data collected by Daiichi Sankyo in the Phase 1 trial, *i.e.*, <20 patients. FE1 further explained that Vellanki and Bryce were aware of the Phase 1 trial data and the limitations it presented. FE1 said that Vellanki understood that Daiichi Sankyo's Phase 1 trial recommended a Phase 2 dosing schedule and not a Phase 3 dosing schedule. FE1 also said that Bryce, who is a seasoned drug development executive, likewise understood the results and data from the Phase 1 trial and the fact that it recommended a Phase 2 dose instead of a Phase 3 dose. According to FE1, Vellanki and Bryce had substantial experience and consequently understood the data they had, its limitations, and the import of the decisions they were making.

64. Rain's competitors, who were developing similar drug candidates for similar treatments, followed the ordinary progression of the clinical trial process. Kartos Therapeutics, Aileron Therapeutics Inc., Ascentage Pharma Group, Boehringer Ingelheim, Astex

Pharmaceuticals, or Novartis AG were either conducting dose escalation trials or pursuing other indications, such as myelofibrosis (Kartos' KRT-232/AMG-232), hematologic malignancies (Roche Holding AG's idasanutlin), or chemotherapy protectants (Aileron Therapeutics' 6924). None was willing to contravene the customary practices, industry standards, or academic literature by engaging in a Phase 2 Bypass.

65. Notwithstanding the foregoing, Defendants repeatedly referred to the Phase 2 Bypass as a benefit instead of disclosing the acute risks it created. Defendants' failure to inform the market about these risks was an extreme departure from the standards of ordinary care that presented a danger of misleading buyers and sellers of Rain's stock that was either known to Defendants or was so obvious that they must have been aware of it.

FALSE AND MATERIALLY MISLEADING STATEMENTS

April 23, 2021

66. On April 23, 2021, Rain filed its final prospectus in conjunction with its initial public offering. Rain's prospectus represented in no less than three separate instances that the trial data from Daiichi Sankyo's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the prospectus stated as follows:

> Our lead product candidate, RAIN-32 (milademetan, formerly known as DS-3032), is a small molecule, oral inhibitor of mouse double minute 2 (MDM2), which is oncogenic in numerous cancers. We in-licensed RAIN-32 in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors. This trial also ***validated a rationally-designed dosing schedule*** that has been shown to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition, unlocking the potential for RAIN-32 in a broad range of MDM2-dependent cancers. ***Based on these data, we anticipate commencing a pivotal Phase 3 trial in LPS in the second half of 2021*** . . . .

(emphasis added)

67. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not "validate[]" a "dosing schedule" or support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. The Phase 1 trial identified a dose for further testing, *i.e.*, the recommended Phase 2 dose, and therefore had not been "validated" or otherwise "shown to mitigate safety concerns" as represented. Further, Phase 2 Bypass is only

appropriate where the drug's mechanism of action and safety profile are well characterized. Milademetan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

May 25, 2021

68. On May 25, 2021, Rain filed its quarterly report on Form 10-Q with the SEC. Vellanki signed the report on behalf of Rain. Vellanki also certified the contents of the report pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, stating in pertinent part that the report did not contain any untrue statements of material fact.

69. Rain's quarterly report represented that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the prospectus stated as follows:

> Our lead product candidate, RAIN-32 (milademetan), is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. We in-licensed RAIN-32 in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of LPS and other solid tumors. Data from well-differentiated/de-differentiated (WD/DD) liposarcoma (LPS) patients in the Phase 1 clinical trial of RAIN-32 demonstrated median progression-free survival (mPFS) approximately three to four times greater than trabectedin or eribulin, the current standard of care (SOC). Importantly, this result was accomplished with a rationally-designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for RAIN-32 in a broad range of MDM2-dependent cancers. ***Based on these data, we anticipate commencing a pivotal Phase 3 trial in LPS in the second half of 2021*** . . . .

(emphasis added)

70. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. Phase 2 Bypass is only appropriate where the drug's mechanism of action and safety profile are well characterized. Miladametan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

July 20, 2021

71. On July 20, 2021, Rain issued a press release announcing the initiation of the Company's Phase 3 MANTRA clinical trial. The press release quoted Bryce promoting the Phase 2 Bypass. In pertinent part, the press release stated as follows:

> NEWARK, Calif., July 20, 2021 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc., a clinical-stage company developing precision oncology therapeutics, today announced that the first patient has been randomized in the multicenter, open-label, Phase 3 registrational study (MANTRA) evaluating milademetan (RAIN-32), an oral mouse double minute 2 (MDM2) inhibitor, for the treatment of DD LPS.
>
> "The start of our Phase 3 MANTRA study evaluating milademetan marks an important step forward in addressing a high unmet need for patients with DD LPS," said Richard Bryce, MBChB, Chief Medical Officer at Rain Therapeutics. "***We are proud to have advanced milademetan into a pivotal study less than 12 months after acquiring the program***, and believe it has the potential to be ***the best-in-class MDM2 inhibitor***."

(emphasis added)

72. The statements identified above in emphasis were false and/or materially misleading. Although Bryce in the press release refers to commencing the "pivotal study less than 12 months after acquiring the program" as a positive achievement for the Company, the Phase 2 Bypass was in fact an extremely reckless maneuver. The Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature that was not a positive development but instead a reckless gamble that exposed investors to extreme risk. The press release misled investors by referring to the Phase 2 Bypass positively while at the same time concealing the risks it created for investors. In addition, Bryce refers to milademetan as having the "potential to be the best-in-class MDM2 inhibitor," which the SEC explicitly prohibited Rain from stating just months earlier in connection with the Company's initial public offering. Defendants did not have a factual basis for making any statements regarding the regulatory approval or safety, tolerability and efficacy of milademetan at the time of the initial public offering given the current stage and history of Rain's drug candidates. Nothing had changed by the time of the above press release, except for the initial dosing of the first patient in the Phase 3 MANTRA trial (which was blinded). Thus, Rain continued to lack a factual basis for the statement that milademetan had the "potential to be the best-in-class MDM2 inhibitor."

August 10, 2021

73. On August 10, 2021, Rain filed its quarterly report on Form 10-Q with the SEC. Vellanki signed the report on behalf of Rain. Vellanki also certified the contents of the report pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, stating in pertinent part that the report did not contain any untrue statements of material fact.

74. The quarterly report stated, in pertinent part, that "Rain is a late-stage precision oncology company . . . ." The quarterly report made this representation in two locations; first, within the reports Notes to Condensed Financial Statements and, second, within Management's Discussion and Analysis of Financial Condition and Results of Operations. The representation was false and/or materially misleading.

75. Contrary to Rain's representation in the quarterly report, the Company was not a "late" stage company. Rain had only just begun its first clinical trial on July 20, 2021. Outside of that, Rain's only clinical data was from the Phase 1 trial conducted by a third-party, *i.e.*, Daiichi Sankyo. Late-stage clinical trial companies are those that have substantial experience designing, implementing, conducting, and completing clinical trial operations. Rain did not have this experience; to the contrary, Rain had no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. By describing Rain as a "late-stage precision oncology company," Defendants materially misrepresented its clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki just months earlier.

76. Rain's quarterly report also represented that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the quarterly report stated as follows:

> Our lead product candidate, milademetan (RAIN-32), is a small molecule, oral inhibitor of mouse double minute 2 (MDM2), which is oncogenic in numerous cancers. We in-licensed milademetan in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of LPS and other solid tumors. Data from well-differentiated/de-differentiated (WD/DD) liposarcoma (LPS) patients in the Phase 1 clinical trial of milademetan demonstrated median progression-free survival (mPFS) approximately three to four times greater than trabectedin or eribulin, the current standard of care (SOC). Importantly, this result was accomplished with a

> rationally-designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for milademetan in a broad range of MDM2-dependent cancers. ***Based on these data, we commenced a pivotal Phase 3 trial in LPS in July 2021*** . . . .

(emphasis added)

77. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. Phase 2 Bypass is only appropriate where the drug's mechanism of action and safety profile are well characterized. Milademetan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

78. In addition to Rain's quarterly report, the Company also issued a press release announcing its financial results and recent highlights for the quarter. In pertinent part, the press release stated as follows:

> NEWARK, Calif., August 10, 2021 (GLOBE NEWSWIRE) — Rain Therapeutics Inc. ("Rain"), a ***late-stage company*** developing precision oncology therapeutics, today reports financial results for the second quarter and six months ended June 30, 2021, along with an update on the company's key developments, business operations and upcoming milestones.
>
> "Rain has made strong progress in the second quarter and six months ended 2021," said Avanish Vellanki, co-founder and chief executive officer of Rain. "Patients with dedifferentiated liposarcoma are in desperate need of new therapies, and ***we are proud to have been able to dose the first patient in a pivotal Phase 3 trial in under 12 months from acquiring the program***. As we move forward with the milademetan clinical strategy, we look to commence our second trial, MANTRA-2, in patients with MDM2-amplified solid tumors, in the second half of 2021."

(emphasis added)

79. The statements identified above in emphasis were false and/or materially misleading. By referring to itself as a "late-stage company," Defendants materially misrepresented the Company's clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki just months earlier. In addition, although Vellanki in the press release refers to commencing the "pivotal Phase 3 trial in under 12 months from acquiring the program" as a positive achievement for the Company, the Phase 2 Bypass was in fact an extremely reckless

maneuver. The Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature that was not a positive development but instead a reckless gamble that exposed investors to extreme risk. The press release misled investors by referring to the Phase 2 Bypass positively while at the same time concealing the risks it created for investors.

November 10, 2021

80. On November 10, 2021, Rain filed its quarterly report on Form 10-Q with the SEC. Vellanki signed the report on behalf of Rain. Vellanki also certified the contents of the report pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, stating in pertinent part that the report did not contain any untrue statements of material fact.

81. The quarterly report stated, in pertinent part, that "Rain is a late-stage precision oncology company . . . ." The quarterly report made this representation in two locations; first, within the Notes to Condensed Financial Statements and, second, within Management's Discussion and Analysis of Financial Condition and Results of Operations. The representation was false and/or materially misleading.

82. Contrary to Rain's representation in the quarterly report, the Company was not a "late" stage company. Rain had only just begun its first clinical trial on July 20, 2021. Outside of that, Rain's only clinical data was from the Phase 1 trial conducted by a third-party, *i.e.*, Daiichi Sankyo. Late-stage clinical trial companies are those that have substantial experience designing, implementing, conducting, and completing clinical trial operations. Rain did not have this experience; to the contrary, Rain had no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. By describing Rain as a "late-stage precision oncology company," Defendants materially misrepresented its clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki just months earlier.

83. Rain's quarterly report also represented that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the quarterly report stated as follows:

> Our lead product candidate, milademetan is a small molecule, oral inhibitor of mouse double minute 2 (MDM2), which is oncogenic in numerous cancers. We in-licensed milademetan in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of LPS and other solid tumors. Data from well-differentiated/de-differentiated (WD/DD) liposarcoma (LPS) patients in the Phase 1 clinical trial of milademetan demonstrated median progression-free survival (mPFS) of approximately seven to eight months. Importantly, this result was accomplished with a rationally designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for milademetan in a broad range of MDM2-dependent cancers. ***Based on these data, we commenced a pivotal Phase 3 trial in LPS in July 2021***.

(emphasis added)

84. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. Phase 2 Bypass is only appropriate where the drug's mechanism of action and safety profile are well characterized. Milademetan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

85. In addition to Rain's quarterly report, the Company also issued a press release announcing its financial results and recent highlights for the quarter. In pertinent part, the press release stated as follows:

> NEWARK, Calif., Nov. 10, 2021 (GLOBE NEWSWIRE) — Rain Therapeutics Inc. (NasdaqGS: RAIN), (Rain), a ***late-stage company*** developing precision oncology therapeutics, today reports financial results for the third quarter and nine months ended September 30, 2021, along with an update on the company's key developments, business operations and upcoming milestones.

(emphasis added)

86. The statements identified above in emphasis were false and/or materially misleading. By referring to itself as a "late-stage company," Defendants materially misrepresented

the Company's clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki just months earlier.

March 3, 2022

87. On March 3, 2022, Rain filed its annual report for fiscal 2021 on Form 10-K with the SEC. Vellanki signed the report on behalf of Rain. Vellanki also certified the contents of the report pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, stating in pertinent part that the report did not contain any untrue statements of material fact.

88. The annual report stated, in pertinent part, that "Rain is a late-stage precision oncology company . . . ." The annual report made this representation in three locations; first, when describing the Company in the Company Overview section, second, within Notes to Condensed Financial Statements and, third, within Management's Discussion and Analysis of Financial Condition and Results of Operations. The representation was false and/or materially misleading.

89. Contrary to Rain's representation in the quarterly report, the Company was not a "late" stage company. Rain had only just begun its first clinical trial on July 20, 2021. Outside of that, Rain's only clinical data was from the Phase 1 trial conducted by a third-party, *i.e.*, Daiichi Sankyo. Late-stage clinical trial companies are those that have substantial experience designing, implementing, conducting, and completing clinical trial operations. Rain did not have this experience; to the contrary, Rain had no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. By describing Rain as a "late-stage precision oncology company," Defendants materially misrepresented its clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki just months earlier.

90. Rain's annual report also represented that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the quarterly report stated as follows:

> Our lead product candidate, milademetan (also known as RAIN-32) is a small molecule, oral inhibitor of mouse double minute 2 (MDM2), which may be oncogenic in numerous cancers. We in-licensed milademetan from Daiichi Sankyo in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of

> liposarcoma (LPS) and other solid tumors. Data from well-differentiated/de-differentiated (WD/DD) liposarcoma LPS patients in the Phase 1 clinical trial of milademetan demonstrated median progression-free survival (mPFS) of approximately seven to eight months. Importantly, this result was accomplished with a rationally designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for milademetan in a broad range of MDM2-dependent cancers. ***Based on these data, we commenced a pivotal Phase 3 trial in LPS (MANTRA) in July 2021***.

(emphasis added)

91. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. Phase 2 Bypass is only appropriate where the drug's mechanism of action and safety profile are well characterized. Milademetan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

92. Rain's annual report further described Daiichi Sanyko's Phase 1 data, claiming that it "validated" the dosing schedule being used in the Phase 3 trial. In pertinent part, the annual report stated:

> Milademetan has been evaluated by Daiichi Sankyo in various solid tumors, including WD/DD LPS, in a Phase 1 trial (U101) for initial assessment of safety, tolerability and preliminary efficacy. The largest population enrolled in the trial were WD/DD LPS patients (approximately 50% of the total patients enrolled). WD/DD LPS tumors have nearly universal MDM2 gene amplification and WT p53, and hence are nearly universally MDM2-dependent. Therefore, we believe these LPS patients represent an appropriate population for MDM2 inhibition therapy. In October 2020, Daiichi Sankyo reported comprehensive results from this Phase 1 trial covering 107 patients. Miladematan has demonstrated meaningful antitumor activity in an MDM2-amplified subtype of LPS and other solid tumors in a Phase 1 clinical trial, ***validating a rationally-designed dosing schedule*** to potentially mitigate safety concerns and widen the therapeutic window of MDM2 inhibition.

(emphasis added)

93. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not "validate[]" a "dosing schedule" or support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. The Phase 1 trial identified a dose for further testing, *i.e.*, the recommended Phase 2 dose, and therefore had not "validat[ed]" the dose or otherwise demonstrated it "mitigate[d] safety concerns" as represented.

94. Rain also included within its annual report the following diagram illustrating the status of the Company's "Development Pipeline":

95. The "Development Pipeline" table within Rain's annual report was materially misleading. Rain had no role in milademetan's Phase 1 clinical trial and did not conduct a Phase 2 trial. However, the above table indicates that Rain was responsible for and conducted both Phase 1 and Phase 2 testing. Defendants attempted to include a table substantially similar to the one above in Rain's registration statement and prospectus but the SEC prohibited them from doing so because it "[did] not accurately portray the company's role in the trials shown or the actual progress to date of the candidates." The SEC required Rain to revise the table to "only reflect completed trials in the phase columns . . . and clearly source the completed Phase 1 trial to Daiichi Sanky[o]." By including the above table in the annual report, Defendants falsely implied to investors that Rain had conducted all pre-clinical and clinical trial testing when, in fact, the Company had not.

96. In addition to Rain's annual report, the Company also issued a press release announcing its financial results and recent highlights for the year. In pertinent part, the press release stated as follows:

> NEWARK, Calif., March 3, 2022 (GLOBE NEWSWIRE) — Rain Therapeutics Inc. (NasdaqGS: RAIN), (Rain), a ***late-stage*** company developing precision oncology therapeutics, today reports financial results for the fourth quarter and full year ended December 31, 2021, along with an update on the Company's key developments, business operations and upcoming milestones.
>
> "***Rain has achieved a number of important clinical milestones for milademetan*** including commencing two of the four planned trials in MDM2-dependent cancers. ***Rain dosed the first patient in the third quarter of last year*** and exceeded year-

> end 2021 targets for site activations for the pivotal, Phase 3 MANTRA trial in patients with liposarcoma and dosed the first patient in our Phase 2 MANTRA-2 basket trial in genetically selected patients with MDM2 gene amplification. We have also outlined two additional trials to start in the second half of this year, including the MANTRA-3 trial in patients with Merkel cell carcinoma, and our first combination trial MANTRA-4, with Roche's anti-PD-L1 antibody, atezolizumab, in patients with advanced cancers exhibiting loss of the CDKN2A gene," said Avanish Vellanki, co-founder and chief executive officer of Rain.

(emphasis added)

97. The statements identified above in emphasis were false and/or materially misleading. By referring to itself as a "late-stage company," Defendants materially misrepresented the Company's clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki the previous year. In addition, although Vellanki in the press release refers to commencing the Phase 3 trial as an "important clinical milestone for milademetan," the Phase 2 Bypass was in fact an extremely reckless maneuver. The Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature that was not a positive development but instead a reckless gamble that exposed investors to extreme risk. The press release misled investors by referring to the Phase 2 Bypass positively while at the same time concealing the risks it created for investors.

May 4, 2022

98. On May 4, 2022, Rain filed its quarterly report on Form 10-Q with the SEC. Vellanki signed the report on behalf of Rain. Vellanki also certified the contents of the report pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, stating in pertinent part that the report did not contain any untrue statements of material fact.

99. The quarterly report stated, in pertinent part, that "Rain is a late-stage precision oncology company . . . ." The quarterly report made this representation in two locations; first, within the Notes to Condensed Financial Statements and, second, within Management's Discussion and Analysis of Financial Condition and Results of Operations. The representation was false and/or materially misleading.

100. Contrary to Rain's representation in the quarterly report, the Company was not a "late" stage company. Rain had only just begun its first clinical trial on July 20, 2021. Outside of that, Rain's only clinical data was from the Phase 1 trial conducted by a third-party, *i.e.*, Daiichi

Sankyo. Late-stage clinical trial companies are those that have substantial experience designing, implementing, conducting, and completing clinical trial operations. Rain did not have this experience; to the contrary, Rain had no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. By describing Rain as a "late-stage precision oncology company," Defendants materially misrepresented its clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki during Rain's initial public offering.

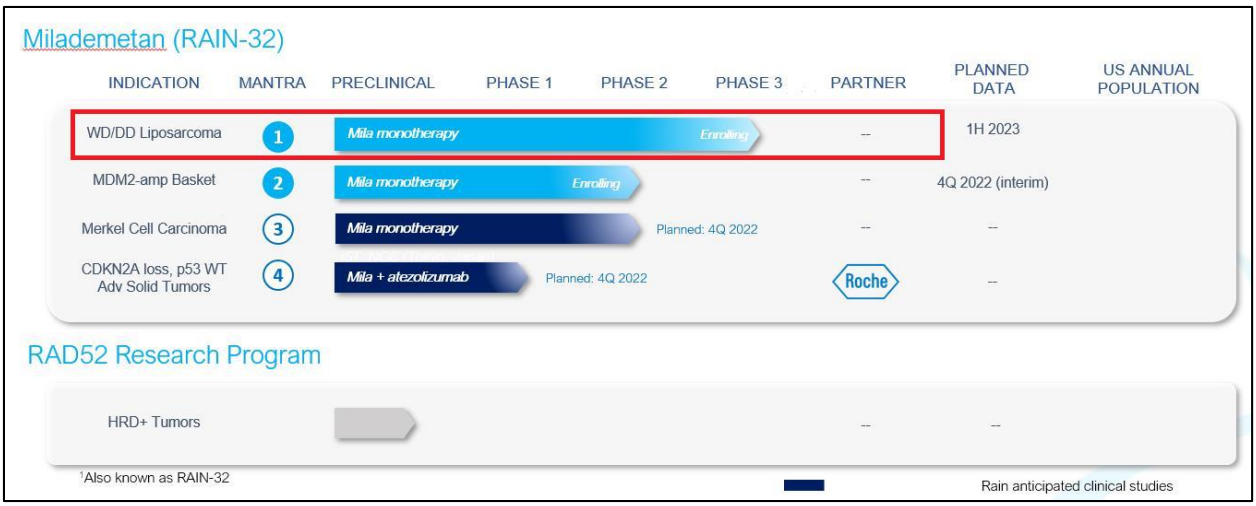
101. Rain's quarterly report also represented that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the quarterly report stated as follows:

> Our lead product candidate, milademetan (also known as RAIN-32) is a small molecule, oral inhibitor of mouse double minute 2 (MDM2), which may be oncogenic in numerous cancers. We in-licensed milademetan from Daiichi Sankyo in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors. Data from well-differentiated/de-differentiated (WD/DD) LPS patients in the Phase 1 clinical trial of milademetan demonstrated median progression-free survival (mPFS) of approximately seven to eight months. Importantly, this result was accomplished with a rationally designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for milademetan in a broad range of MDM2-dependent cancers. ***Based on these data, we commenced a pivotal Phase 3 trial in LPS (MANTRA) in July 2021***.

(emphasis added)

102. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. Phase 2 Bypass is only appropriate where the drug's mechanism of action and safety profile are well characterized. Miladametan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

103. Rain also included within its quarterly report the following diagram illustrating the status of the Company's "Development Pipeline":



104. The "Development Pipeline" table within Rain's quarterly report was materially misleading. Rain had no role in miladametan's Phase 1 clinical trial and did not conduct a Phase 2 trial. However, the above table indicates that Rain was responsible for and conducted both Phase 1 and Phase 2 testing. Defendants attempted to include a table substantially similar to the one above in Rain's registration statement and prospectus but the SEC prohibited them from doing so because it "[did] not accurately portray the company's role in the trials shown or the actual progress to date of the candidates." The SEC required Rain to revise the table to "only reflect completed trials in the phase columns . . . and clearly source the completed Phase 1 trial to Daiichi Sanky[o]." By including the above table in the quarterly report, Defendants falsely implied to investors that Rain had conducted all pre-clinical and clinical trial testing when, in fact, the Company had not.

105. In addition to Rain's quarterly report, the Company also issued a press release announcing its financial results and recent highlights for the quarter. In pertinent part, the press release stated as follows:

> NEWARK, Calif., May 4, 2022 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc. (NasdaqGS: RAIN), (Rain), a ***late-stage biotechnology company*** developing precision oncology therapeutics, today reports financial results for the first quarter ended March31, 2022, along with an update on the Company's key developments, business operations and upcoming milestones.

(emphasis added)

106. The statements identified above in emphasis were false and/or materially misleading. By referring to itself as a "late-stage biotechnology company," Defendants materially misrepresented the Company's clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki during Rain's initial public offering.

August 4, 2022

107. On August 4, 2022, Rain filed its quarterly report on Form 10-Q with the SEC. Vellanki signed the report on behalf of Rain. Vellanki also certified the contents of the report pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, stating in pertinent part that the report did not contain any untrue statements of material fact.

108. The quarterly report stated, in pertinent part, that "Rain is a late-stage precision oncology company . . . ." The quarterly report made this representation in two locations; first, within the Notes to Condensed Financial Statements and, second, within Management's Discussion and Analysis of Financial Condition and Results of Operations. The representation was false and/or materially misleading.

109. Contrary to Rain's representation in the quarterly report, the Company was not a "late" stage company. Rain had only just begun its first clinical trial on July 20, 2021. Outside of that, Rain's only clinical data was from the Phase 1 trial conducted by a third-party, *i.e.*, Daiichi Sankyo. Late-stage clinical trial companies are those that have substantial experience designing, implementing, conducting, and completing clinical trial operations. Rain did not have this experience; to the contrary, Rain had no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. By describing Rain as a "late-stage precision oncology company," Defendants materially misrepresented its clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki during Rain's initial public offering.

110. Rain's quarterly report also represented that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the quarterly report stated as follows:

> Our lead product candidate, milademetan (also known as RAIN-32) is an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53. We in-licensed

> miladametan from Daiichi Sankyo in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors. Data from well-differentiated/de-differentiated (WD/DD) LPS patients in the Phase 1 clinical trial of miladametan demonstrated median progression-free survival (mPFS) of approximately seven to eight months. Importantly, this result was accomplished with a rationally designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for miladametan in a broad range of MDM2-dependent cancers. ***Based on these data, we commenced a pivotal Phase 3 trial in LPS (MANTRA) in July 2021***.

(emphasis added)

111. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. Phase 2 Bypass is only appropriate where the drug's mechanism of action and safety profile are well characterized. Miladametan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

112. Rain also included within its quarterly report the following diagram illustrating the status of the Company's "Development Pipeline":

113. The "Development Pipeline" table within Rain's quarterly report was materially misleading. Rain had no role in miladametan's Phase 1 clinical trial and did not conduct a Phase 2 trial. However, the above table indicates that Rain was responsible for and conducted both Phase 1 and Phase 2 testing. Defendants attempted to include a table substantially similar to the one above in Rain's registration statement and prospectus but the SEC prohibited them from doing so

because it "[did] not accurately portray the company's role in the trials shown or the actual progress to date of the candidates." The SEC required Rain to revise the table to "only reflect completed trials in the phase columns . . . and clearly source the completed Phase 1 trial to Daiichi Sanky[o]." By including the above table in the quarterly report, Defendants falsely implied to investors that Rain had conducted all pre-clinical and clinical trial testing when, in fact, the Company had not.

114. In addition to Rain's quarterly report, the Company also issued a press release announcing its financial results and recent highlights for the quarter. In pertinent part, the press release stated as follows:

> NEWARK, Calif., August 4, 2022 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc. (NasdaqGS:RAIN), (Rain), a ***late-stage biotechnology company*** developing precision oncology therapeutics with a lead product candidate, milademetan, an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53, today reported financial results for the second quarter and six months ended June 30, 2022,along with an update on the Company's key developments, business operations and upcoming milestones.

(emphasis added)

115. The statements identified above in emphasis were false and/or materially misleading. By referring to itself as a "late-stage biotechnology company," Defendants materially misrepresented the Company's clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki during Rain's initial public offering.

November 10, 2022

116. On November 10, 2022, Rain filed its quarterly report on Form 10-Q with the SEC. Vellanki signed the report on behalf of Rain. Vellanki also certified the contents of the report pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, stating in pertinent part that the report did not contain any untrue statements of material fact.

117. The quarterly report stated, in pertinent part, that "Rain is a late-stage precision oncology company . . . ." The quarterly report made this representation in two locations; first, within the Notes to Condensed Financial Statements and, second, within Management's Discussion and Analysis of Financial Condition and Results of Operations. The representation was false and/or materially misleading.

118. Contrary to Rain's representation in the quarterly report, the Company was not a "late" stage company. Rain had only just begun its first clinical trial on July 20, 2021. Outside of that, Rain's only clinical data was from the Phase 1 trial conducted by a third-party, *i.e.*, Daiichi Sankyo. Late-stage clinical trial companies are those that have substantial experience designing, implementing, conducting, and completing clinical trial operations. Rain did not have this experience; to the contrary, Rain had no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. By describing Rain as a "late-stage precision oncology company," Defendants materially misrepresented its clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki during Rain's initial public offering.

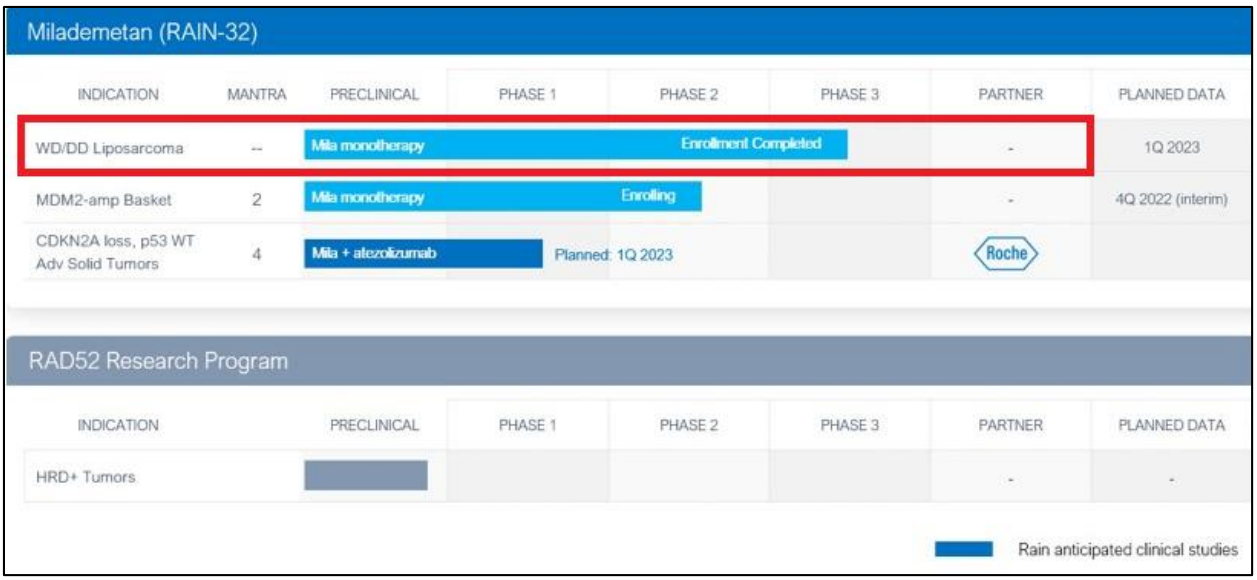
119. Rain's quarterly report also represented that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the quarterly report stated as follows:

> Our lead product candidate, milademetan (also known as RAIN-32) is an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53. We in-licensed milademetan from Daiichi Sankyo in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors. Data from well-differentiated/de-differentiated (WD/DD) LPS patients in the Phase 1 clinical trial of milademetan demonstrated median progression-free survival (mPFS) of approximately seven to eight months. Importantly, this result was accomplished with a rationally designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for milademetan in a broad range of MDM2-dependent cancers. ***Based on these data, we commenced a pivotal Phase 3 trial in LPS (MANTRA) in July 2021***.

(emphasis added)

120. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. Phase 2 Bypass is only appropriate where the drug's mechanism of action and safety profile are well characterized. Miladametan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

121. Rain also included within its quarterly report the following diagram illustrating the status of the Company's "Development Pipeline":



122. The "Development Pipeline" table within Rain's quarterly report was materially misleading. Rain had no role in milademetan's Phase 1 clinical trial and did not conduct a Phase 2 trial. However, the above table indicates that Rain was responsible for and conducted both Phase 1 and Phase 2 testing. Defendants attempted to include a table substantially similar to the one above in Rain's registration statement and prospectus but the SEC prohibited them from doing so because it "[did] not accurately portray the company's role in the trials shown or the actual progress to date of the candidates." The SEC required Rain to revise the table to "only reflect completed trials in the phase columns . . . and clearly source the completed Phase 1 trial to Daiichi Sanky[o]." By including the above table in the quarterly report, Defendants falsely implied to investors that Rain had conducted all pre-clinical and clinical trial testing when, in fact, the Company had not.

123. In addition to Rain's quarterly report, the Company also issued a press release announcing its financial results and recent highlights for the quarter. In pertinent part, the press release stated as follows:

> NEWARK, Calif., November 10,2022 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc. (NasdaqGS: RAIN), (Rain), a ***late-stage biotechnology company*** developing precision oncology therapeutics with a lead product candidate, milademetan, an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53, today reported financial results for the third quarter ended September 30, 2022, along with an update on the Company's key developments, business operations and upcoming milestones.

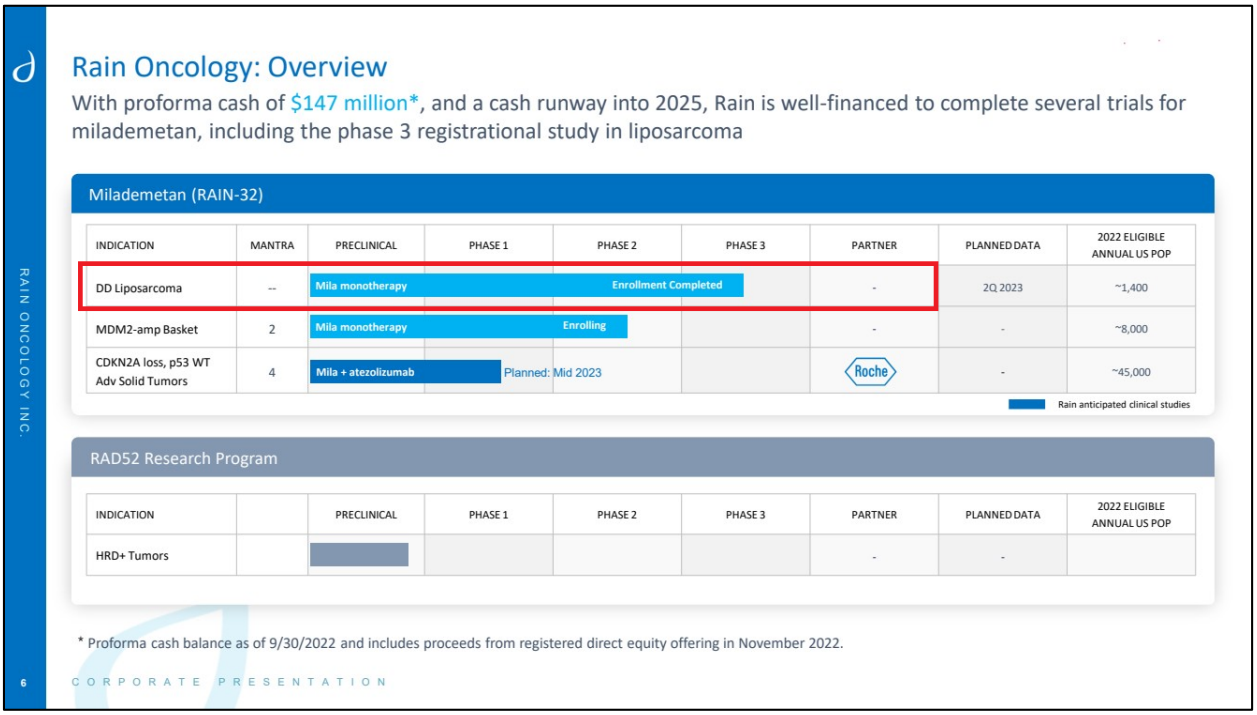
(emphasis added)

124. The statements identified above in emphasis were false and/or materially misleading. By referring to itself as a "late-stage biotechnology company," Defendants materially misrepresented the Company's clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki during Rain's initial public offering.

February 9, 2023

125. On February 9, 2023, Rain participated in a "fireside chat" at the Guggenheim Healthcare Talks Oncology Day Conference.

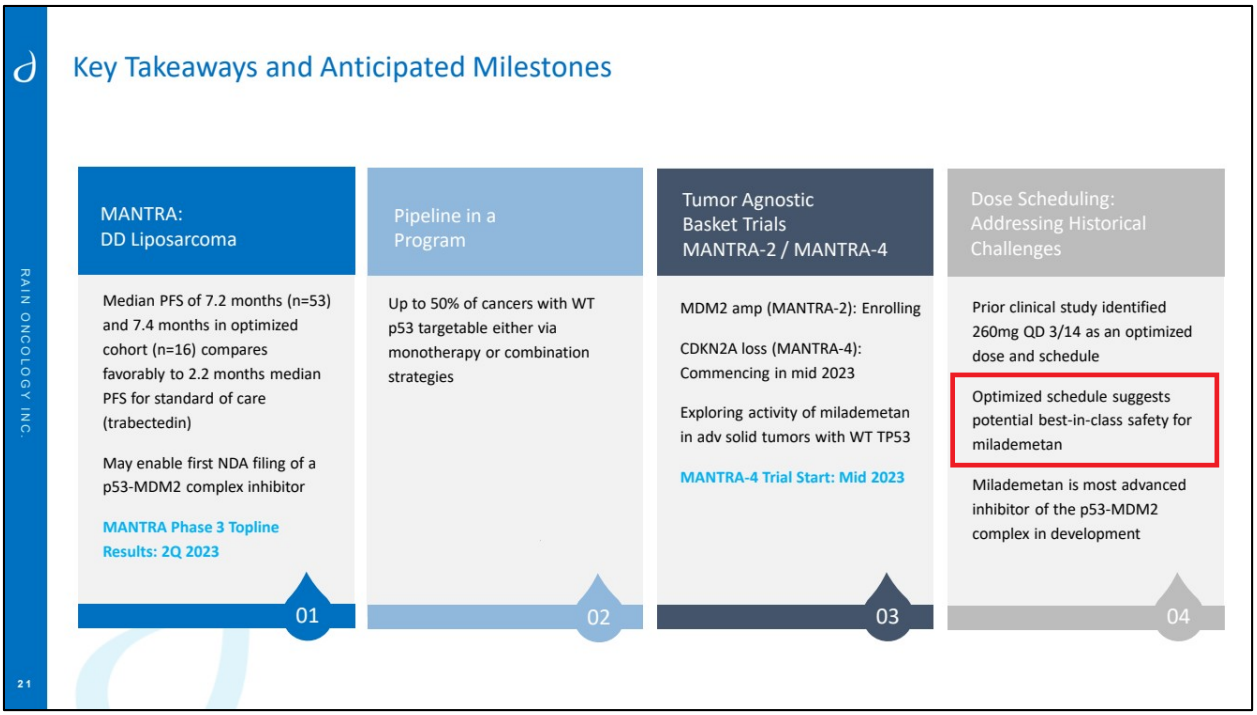
126. Rain's corporate presentation featured the following slide, which materially misrepresented the Company's clinical trial operations:



127. The slide within Rain's corporate presentation was materially misleading. Rain had no role in miladametan's Phase 1 clinical trial and did not conduct a Phase 2 trial. However, the above table indicates that Rain was responsible for and conducted both Phase 1 and Phase 2 testing. Defendants attempted to include a table substantially similar to the one above in Rain's registration statement and prospectus but the SEC prohibited them from doing so because it "[did] not accurately portray the company's role in the trials shown or the actual progress to date of the candidates." The SEC required Rain to revise the table to "only reflect completed trials in the phase

columns . . . and clearly source the completed Phase 1 trial to Daiichi Sanky[o].” By including the above table in the presentation, Defendants falsely implied to investors that Rain had conducted all pre-clinical and clinical trial testing when, in fact, the Company had not.

128. Rain’s corporate presentation also referred to miladametan as being the “best-in-class” for safety, as demonstrated below:



129. Rain refers to miladametan as having the potential to be the “best-in-class” MDM2 inhibitor, which the SEC explicitly prohibited Rain from stating during the Company’s initial public offering. Defendants did not have a factual basis for making any statements regarding the regulatory approval or safety, tolerability and efficacy of miladametan at the time of the initial public offering given the current stage and history of Rain’s drug candidates. Nothing had changed by the time of the above press release and no results had been obtained from Phase 3 MANTRA trial (which was blinded). Thus, Rain continued to lack a factual basis for the statement that miladametan had the potential to be the “best-in-class” MDM2 inhibitor.

March 9, 2023

130. On March 9, 2023, Rain filed its annual report for fiscal 2022 on Form 10-K with the SEC. Vellanki signed the report on behalf of Rain. Vellanki also certified the contents of the

report pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, stating in pertinent part that the report did not contain any untrue statements of material fact.

131. The annual report stated, in pertinent part, that "Rain is a late-stage precision oncology company . . . ." The annual report made this representation in three locations; first, when describing the Company in the Company Overview section, second, within Notes to Condensed Financial Statements and, third, within Management's Discussion and Analysis of Financial Condition and Results of Operations. The representation was false and/or materially misleading.

132. Contrary to Rain's representation in the quarterly report, the Company was not a "late" stage company. Rain had only just begun its first clinical trial on July 20, 2021. Outside of that, Rain's only clinical data was from the Phase 1 trial conducted by a third-party, *i.e.*, Daiichi Sankyo. Late-stage clinical trial companies are those that have substantial experience designing, implementing, conducting, and completing clinical trial operations. Rain did not have this experience; to the contrary, Rain had no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. By describing Rain as a "late-stage precision oncology company," Defendants materially misrepresented its clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki just months earlier.

133. Rain's annual report also represented that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the quarterly report stated as follows:

> Our lead product candidate, milademetan (also known as RAIN-32) is an oral, small molecule inhibitor of the mouse double minute 2 (MDM2-p53) complex that reactivates p53. We in-licensed milademetan from Daiichi Sankyo Company, Limited (Daiichi Sankyo) in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors. Data from de-differentiated liposarcoma (DDLPS) patients in the Phase 1 clinical trial of milademetan demonstrated median progression-free survival (mPFS) of approximately seven to eight months. Importantly, this result was accomplished with a rationally designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for milademetan in a broad range of MDM2-dependent cancers. ***Based on these data, we commenced a pivotal Phase 3 trial in LPS (MANTRA) in July 2021***.

(emphasis added)

134. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. Phase 2 Bypass is only appropriate where the drug's mechanism of action and safety profile are well characterized. Milademetan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

135. Rain's annual report further described Daiichi Sanyko's Phase 1 data, claiming that it "validated" the dosing schedule being used in the Phase 3 trial. In pertinent part, the annual report stated:

> Milademetan has been evaluated by Daiichi Sankyo in various solid tumors, including DDLPS, in a Phase 1 trial (U101) for initial assessment of safety, tolerability and preliminary efficacy. The largest population enrolled in the trial were DDLPS patients (approximately 50% of the total patients enrolled). DDLPS tumors have nearly universal MDM2 gene amplification and WT p53, and hence are nearly universally MDM2-dependent. Therefore, we believe these LPS patients represent an appropriate population for MDM2 inhibition therapy. In October 2020, Daiichi Sankyo reported comprehensive results from this Phase 1 trial covering 107 patients. Milademetan has demonstrated meaningful antitumor activity in an MDM2-amplified subtype of LPS and other solid tumors in a Phase 1 clinical trial, ***validating a rationally-designed dosing schedule*** to potentially mitigate safety concerns and widen the therapeutic window of MDM2 inhibition.

(emphasis added)

136. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not "validate[]" a "dosing schedule" or support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. The Phase 1 trial identified a dose for further testing, *i.e.*, the recommended Phase 2 dose, and therefore had not "validat[ed]" the dose or otherwise demonstrated it "mitigate[d] safety concerns" as represented.

137. Rain also included within its annual report the following diagram illustrating the status of the Company's "Development Pipeline":

138. The "Development Pipeline" table within Rain's annual report was materially misleading. Rain had no role in milademetan's Phase 1 clinical trial and did not conduct a Phase 2 trial. However, the above table indicates that Rain was responsible for and conducted both Phase 1 and Phase 2 testing. Defendants attempted to include a table substantially similar to the one above in Rain's registration statement and prospectus but the SEC prohibited them from doing so because it "[did] not accurately portray the company's role in the trials shown or the actual progress to date of the candidates." The SEC required Rain to revise the table to "only reflect completed trials in the phase columns . . . and clearly source the completed Phase 1 trial to Daiichi Sanky[o]." By including the above table in the annual report, Defendants falsely implied to investors that Rain had conducted all pre-clinical and clinical trial testing when, in fact, the Company had not.

139. In addition to Rain's annual report, the Company also issued a press release announcing its financial results and recent highlights for the year. In pertinent part, the press release stated as follows:

> NEWARK, Calif., March 9, 2023 (GLOBE NEWSWIRE) -- Rain Oncology Inc. (NasdaqGS: RAIN), (Rain), a ***late-stage biotechnology company*** developing precision oncology therapeutics with a lead product candidate, milademetan, an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53, today reports financial results for the fourth quarter and full year ended December 31, 2022, along with an update on the Company's key corporate highlights and upcoming milestones.

(emphasis added)

140. The statements identified above in emphasis were false and/or materially misleading. By referring to itself as a "late-stage biotechnology company," Defendants materially

misrepresented the Company's clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki during Rain's initial public offering.

May 11, 2023

141. On May 11, 2023, Rain filed its quarterly report on Form 10-Q with the SEC. Vellanki signed the report on behalf of Rain. Vellanki also certified the contents of the report pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, stating in pertinent part that the report did not contain any untrue statements of material fact.

142. The quarterly report stated, in pertinent part, that "Rain is a late-stage precision oncology company . . . ." The quarterly report made this representation in two locations; first, within the Notes to Condensed Financial Statements and, second, within Management's Discussion and Analysis of Financial Condition and Results of Operations. The representation was false and/or materially misleading.

143. Contrary to Rain's representation in the quarterly report, the Company was not a "late" stage company. Rain had only just begun its first clinical trial on July 20, 2021. Outside of that, Rain's only clinical data was from the Phase 1 trial conducted by a third-party, *i.e.*, Daiichi Sankyo. Late-stage clinical trial companies are those that have substantial experience designing, implementing, conducting, and completing clinical trial operations. Rain did not have this experience; to the contrary, Rain had no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. By describing Rain as a "late-stage precision oncology company," Defendants materially misrepresented its clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki during Rain's initial public offering.

144. Rain's quarterly report also represented that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the quarterly report stated as follows:

> Our lead product candidate, milademetan (also known as RAIN-32) is an oral, small molecule inhibitor of the mouse double minute 2 (MDM2)-p53 complex that reactivates p53. We in-licensed milademetan from Daiichi Sankyo Company, Limited (Daiichi Sankyo) in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-

> amplified subtype of liposarcoma (LPS) and other solid tumors. Data from de-differentiated liposarcoma (DDLPS) patients in the Phase 1 clinical trial of milademetan demonstrated median progression-free survival (mPFS) of approximately seven to eight months. Importantly, this result was accomplished with a rationally designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for milademetan in a broad range of MDM2-dependent cancers. ***Based on these data, we commenced a pivotal Phase 3 trial in LPS (MANTRA) in July 2021***.

(emphasis added)

145. The statements identified above in emphasis were false and/or materially misleading. In truth, Daiichi Sanyko's Phase 1 data did not support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. Phase 2 Bypass is only appropriate where the drug's mechanism of action and safety profile are well characterized. Milademetan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing. In this regard, the Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature.

146. Rain also included within its quarterly report the following diagram illustrating the status of the Company's "Development Pipeline":

147. The "Development Pipeline" table within Rain's quarterly report was materially misleading. Rain had no role in milademetan's Phase 1 clinical trial and did not conduct a Phase 2 trial. However, the above table indicates that Rain was responsible for and conducted both Phase 1 and Phase 2 testing. Defendants attempted to include a table substantially similar to the one above in Rain's registration statement and prospectus but the SEC prohibited them from doing so because it "[did] not accurately portray the company's role in the trials shown or the actual progress to date of the candidates." The SEC required Rain to revise the table to "only reflect completed trials in the phase columns . . . and clearly source the completed Phase 1 trial to Daiichi Sanky[o]."

By including the above table in the quarterly report, Defendants falsely implied to investors that Rain had conducted all pre-clinical and clinical trial testing when, in fact, the Company had not.

148. In addition to Rain's quarterly report, the Company also issued a press release announcing its financial results and recent highlights for the quarter. In pertinent part, the press release stated as follows:

> NEWARK, Calif., May 11, 2023 (GLOBE NEWSWIRE) -- Rain Oncology Inc. (NasdaqGS: RAIN), (Rain), a ***late-stage biotechnology company*** developing precision oncology therapeutics with a lead candidate, milademetan, an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53, today reports financial results for the first quarter ended March 31, 2023, along with an update on the Company's key corporate highlights and upcoming milestones.

(emphasis added)

149. The statements identified above in emphasis were false and/or materially misleading. By referring to itself as a "late-stage biotechnology company," Defendants materially misrepresented the Company's clinical trial experience to investors and directly contradicted warnings from the SEC sent to Vellanki during Rain's initial public offering.

ADDITIONAL SCIENTER ALLEGATIONS

The Individual Defendants Engaged in a Reckless Gamble.

150. Rain's Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature. As previously alleged, Phase 2 Bypass should not be used except when the drug's mechanism of action and safety profile are well characterized. Milademetan had neither. Daiichi Sankyo's Phase 1 trial was a first-in-human clinical trial, meaning that milademetan had never been tested in humans before, and milademetan as a MDM2 inhibitor was historically associated with severe hematologic events. Thus, milademetan did not have a well-characterized mechanism of action or safety profile. Daiichi Sankyo's original clinical trial plan recognized this; indeed, Rain's Phase 2 Bypass contravened the clinical trial plan developed by Daiichi Sankyo, which called for a Phase 2 trial to test the recommended dose(s) identified during the Phase 1 trial.

151. Clinical trial plans from other MDM2 developers further demonstrate the aberrant nature of Rain's Phase 2 Bypass. Kartos Therapeutics, Aileron Therapeutics Inc., Ascentage

Pharma Group, Boehringer Ingelheim, Astex Pharmaceuticals, or Novartis AG were either conducting dose expansion trials or pursuing other indications, such as myelofibrosis (Kartos' KRT-232/AMG-232), hematologic malignancies (Roche Holding AG's idasanutlin), or chemotherapy protectants (Aileron Therapeutics' 6924). None of these developers contravened the customary practices, industry standards, or academic literature by engaging in a Phase 2 Bypass, despite the similarity between their drug candidates and milademetan.

152. Notwithstanding the foregoing, the Individual Defendants applauded their decision to proceed with a Phase 2 Bypass and promoted the Company on that basis while at the same time concealing from investors the excessive clinical trial and regulatory risks it created and how it altered the risk profile associated with investing in the Company. The Individual Defendants' statements led investors to believe that the Phase 2 Bypass was positive for the Company when in fact it was negative. The Individual Defendants concealed material adverse information from investors, *i.e.*, the risks associated with the Phase 2 Bypass, in the hope that it would be overtaken by good news, *i.e.*, successful Phase 3 MANTRA trial results. The Individual Defendants' actions in this regard amounted to a knowing and deliberate reckless gamble.

Rain Needed to Fundraise and Cut Corners to Survive.

153. For the Individual Defendants' gamble to pay off, Rain needed an influx of money to sustain operations long enough to carry the Company through the Phase 3 MANTRA trial. Rain did not have enough operating capital to carry out Daiichi Sankyo's clinical trial plan, which would have entailed conducting a Phase 2 trial that would have taken approximately two years. Consequently, the Individual Defendants were motivated in this regard to engage in the gamble described above and bet the farm because the alternative would have been certain failure.

154. Rain's need for capital was dire because the Company did not have enough money to complete clinical trials for milademetan. Confidential correspondence between Rain and the SEC demonstrate the lengths to which the Individual Defendants and, in particular, Vellanki went to gin up investor interest in the Company's initial public offering. Rain filed its initial draft registration statement on January 29, 2021. On February 24, 2021, the SEC confidentially wrote to Vellanki stating in pertinent part as follows: "We note your statement that you are a 'late

clinical-stage' precision oncology company. However, we also note that you have conducted no clinical trials to date and are relying on data from one Phase 1 trial conducted by a third party. Please provide support for your characterization of the company as a 'late' clinical stage company or revise the reference throughout the prospectus."

155. The SEC further questioned Vellanki on his description of Rain's clinical trials. In pertinent part, the SEC wrote as follows: "We note your pipeline table on pages 4 and 64. We also note the following statement on page 10: 'We have no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. In particular, Daiichi Sankyo conducted the Phase 1 trial for our lead product candidate, RAIN-32, prior to our in-license of RAIN-32 in September 2020.' Based on this statement, your pipeline table does not accurately portray the company's role in the trials shown or the actual progress to date of the candidates. Please revise the table to only reflect completed trials in the phase columns, removing planned trials as progress bars, and clearly source the completed Phase 1 trial to Daiichi Sanky[o]. In relation to planned trials, this information is appropriate in the narrative but as currently depicted in the table implies further progress in the development pipeline than is the case."

156. The SEC also questioned Vellanki's basis for certain claims about milademetan. In pertinent part, the SEC wrote as follows: "Please revise throughout to remove any inference regarding regulatory approval or the safety, tolerability and efficacy of your product candidates or explain to us why these statements are appropriate given the stage of your product candidates. We note, by way of example, the statements: that your lead product candidate, RAIN-32, has 'the potential for a best-in-class profile' on pages 64 and 68; and that your other RAD52 inhibitor candidates are a 'potential first-in-class program' on page 82."

157. On March 5, 2021, Rain's attorneys at Gibson Dunn responded to the SEC, confirming that the Company's registration statement and prospectus would replace all references to "late clinical-stage" with "clinical-stage," revise its pipeline tables to properly depict Rain's clinical trials, and remove all references to the terms "best-in-class" and "first-in-class." Gibson Dunn copied Vellanki and Rain's Chief Scientific Officer, Robert C. Doebele, on the letter.

158. On March 18, 2021, the SEC once again wrote to Vellanki concerning the contents of Rain's draft registration statement and prospectus and, in particular, Rain's description of its clinical trials. The SEC wrote, in pertinent part, as follows: "We note the revisions you made in response to prior comment 3. Please further revise the pipeline table to remove the planned trials. The information with respect to your planned trials may be appropriate as a future milestone and should be addressed in the narrative; however, depicting trials that have not yet occurred in the table implies further progress in the development pipeline than is the case."

159. On April 2, 2021, Gibson Dunn responded to the SEC, confirming that Rain would revise the "pipeline table" at issue in the registration statement and prospectus. Gibson Dunn again copied Vellanki and Mr. Doebele.

160. Rain's "pipeline table" was the subject of one additional back-and-forth with the SEC. On April 8, 2021, the SEC told Vellanki to "identify the phase of the completed trial" in the tables. On April 19, 2021, Gibson Dunn confirmed Rain's compliance with the directive. Vellanki and Mr. Doebele were copied on the response.

161. On no less than three occasions, the SEC objected to Vellanki's statements about Rain and its clinical trial program for mademetan and directed the Company to delete or revise the claims it intended to include in its registration statement and prospectus. Vellanki's efforts to hype Rain's clinical trial plan in spite of the SEC's clear objections demonstrate just how vital the fundraising was in the overall scheme of the Individual Defendants' plan. Fundraising was part and parcel to the success of Defendants' Phase 2 Bypass gamble.

162. FE1 further evidences Vellanki's willingness to mislead investors in pursuit of additional fundraising. As alleged above, FE1 was a Senior Director, Program Management, at Rain from December 2020 to December 2021, who had direct contact with Vellanki and Bryce. FE1 tried to advise Vellanki that he was focusing too heavily and allocating too many resources on mademetan's manufacturing instead of focusing on mademetan's clinical operations, which needed further development. FE1 said that Vellanki did not like being told this. Similarly, FE1 recalled various employees within Rain telling Vellanki not to make certain statements about mademetan and the Company's clinical trials because the statements were not fully supported by

the trial data. Notwithstanding, on more than one occasion while FE1 was employed at Rain, FE1 recalled senior management making statements about the milademetan trials that were exaggerated given that the statements were based upon a small amount of trial data.

163. When Rain conducted its initial public offering, the Company had just recently entered into its license agreement with Daiichi Sankyo for milademetan. The license agreement required Rain to make aggregate future milestone payments of up to $225 million. Meanwhile, Rain's financial statements for the year ended December 31, 2020, reflected a cash balance of only $58.8 million against annual operating expenses of $18.9 million and estimated research and development costs of approximately $90 million through the end of fiscal 2022. Consequently, the successful completion of Rain's initial public offering was vital for Rain to remain a going concern let alone achieve its plan for commercializing milademetan.

164. Rain's initial public offering ended up raising $121.9 million in net proceeds which, according to Rain, was sufficient to fund operations through 2024. However, Rain's operating expenses following the initial public offering were approximately $20 million per quarter. Conducting a Phase 2 trial would have cost approximately $11.2 million (based on average oncology Phase 2 trial costs) as well as extended the time to commercialization by approximately two years, meaning that Rain would have needed hundreds of millions of additional dollars to sustain operations before being able to apply for marketing approval with the FDA and potentially commercialize milademetan (*i.e.*, generate revenue). Specifically, had Rain conducted the Phase 2 trial as initially planned by Daiichi Sankyo, Rain would have needed approximately $160 million in additional funding (*i.e.*, eight quarters of operating expenses at $20 million per quarter plus $11.2 million for the Phase 2 study itself).

165. Conducting a Phase 2 trial would have also allowed for one of Rain's competitors to be first-to-market. Had this occurred, Rain would have needed to meet a higher standard for approval by showing that milademetan's safety and efficacy profile was superior to the competitor drug. Thus, by engaging in the Phase 2 Bypass gamble, Rain attempted to be the first-to-market and force competitor MDM2 drug sponsors to show superiority versus milademetan's clinical profile.

Vellanki Falsely Certified Quarterly Reports under Sarbanes-Oxley.

166. As Rain's CEO, Vellanki signed each of the Company's quarterly and annual reports, including those containing the false and/or materially misleading statements identified above. In addition, Vellanki certified the contents of those reports pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. "Sarbanes-Oxley Certifications," like the ones signed by Vellanki, are required by Congress and the SEC "to facilitate full disclosure and ensure the accuracy of financial reports by requiring corporate executives' personal stamp of approval." 149 Cong. Rec. S5325, S5329 (daily ed. Apr. 11, 2003).

167. In each instance, Vellanki's certifications were knowingly false. Between February 24, 2021 and April 23, 2021, Vellanki received no less than three written letters from the SEC prohibiting him from making certain claims about Rain in the Company's SEC filings, such as that Rain was a "late clinical-stage" oncology company. Contrary to these written warnings, Vellanki proceeded to make these representations about Rain as soon as the initial public offering was complete. Thus, Velanki knew or deliberately disregarded the falsity of his statements in the Company's SEC filings but certified their accuracy notwithstanding.

LOSS CAUSATION AND ECONOMIC LOSS

168. The market for Rain common stock was open, well-developed, and efficient at all relevant times. As a result of Defendants' false and/or materially misleading statements, Rain's stock traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased Rain stock relying upon the integrity of the market and market information related to the Company and have been damaged thereby.

169. The Individual Defendants' false and/or materially misleading statements about Rain's clinical trial strategy and the risks posed by Phase 2 Bypass constituted a scheme to deceive the market and a course of conduct that caused the price of Rain's stock to be artificially inflated. As the Individual Defendants' misrepresentations and fraudulent conduct were gradually disclosed and became apparent to the market, the artificial inflation in the price of Rain's stock was removed, and the price of Rain stock fell. Plaintiffs and other investors sustained damages as the risks

concealed by the Individual Defendants' fraudulent statements materialized and/or the truth emerged concerning Rain's clinical trial strategy.

170. On September 20, 2021, Daiichi Sankyo published results from a separate clinical trial testing milademetan in patients with intimal sarcoma. The trial results reported unusually high rates of hematologic toxicities, including Grade 3 events of thrombocytopenia, neutropenia, white blood cell decreases, and anemia. The results also included a 20% objective response rate. Given that the study participants received 260 mg doses of milademetan, investors perceived the results as a red flag concerning Rain's Phase 2 Bypass and the risks associated with it. In response to the news, Rain's stock price declined from $15.88 per share on September 17, 2021 to $13.21 per share on September 20, 2021.

171. On May 22, 2023, Rain announced the negative trial results for the Phase 3 MANTRA trial. Analysts reported on the results, noting the risks of proceeding directly to a Phase 3 trial from Phase 1. The analysts also noted the high level of Grade 3/4 hematologic adverse events, which suggested that the dosing schedule had not been properly optimized during the Phase 1 trial. Analysts also noted that Rain's Chief Scientific Officer, Robert C. Doebele, acknowledged during a conference call earlier in the day that the 260 mg dose was too high. In response to the news, Rain's stock price declined from $9.93 per share on May 19, 2023 to $1.22 per share on May 22, 2023.

172. The disclosures identified above on September 20, 2021 and May 22, 2023 contradicted Defendants' fraudulent statements and/or revealed to investors (first, in part, and then, in whole) that Rain's clinical trial program presented abnormal, undisclosed, and exceedingly atypical risks given that the Phase 2 Bypass deviated from customary practices, industry standards, and widely-accepted academic literature. Thus, Defendants' acts and omissions proximately caused the decline in Rain's stock price when the truth emerged concerning Rain's clinical trial program.

173. Alternatively, the risks concealed by Defendants about Rain's clinical trial programs materialized and caused investor losses, as demonstrated by the events underlying the disclosures identified above on September 20, 2021 and May 22, 2023. As the risks concerning

Rain's clinical trial programs materialized, the market reevaluated the risks associated with investing in Rain and caused Rain's stock to decrease in value.

174. As a result of their purchases of Rain stock during the Class Period at artificially inflated prices, Plaintiffs and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws.

175. The timing and magnitude of the price decline in Rain stock negate any inference that the loss suffered by Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to the Rain Defendants' fraudulent conduct.

PRESUMPTION OF RELIANCE; FRAUD-ON-THE-MARKET

176. At all relevant times, the market for Rain stock was an efficient market for the following reasons:

(a) Rain 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, Rain filed periodic public reports with the SEC and the Nasdaq;

(c) Rain communicated with public investors via established market communication mechanisms, including through regular dissemination 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) During the Class Period, on average, hundreds of thousands of Rain shares were traded on a weekly basis. On news days, the Company's trading volume increased into the millions, reflecting an active trading market for Rain stock and investors' expectations being impounded into the stock price.

177. As a result of the foregoing, the market for Rain's securities promptly digested current information regarding Rain from all publicly available sources and reflected such

information in Rain's stock price. Under these circumstances, all purchasers of Rain securities during the Class Period suffered similar injury through their purchase of Rain securities at artificially inflated prices, and a presumption of reliance applies.

178. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

NO SAFE HARBOR; INAPPLICABILITY OF BESPEAKS CAUTION DOCTRINE

179. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint.

180. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

181. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Rain who knew that the "forward-looking statement" was false. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions.

182. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this class action Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be

characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Rain who knew that the statement was false when made.

CLASS ACTION ALLEGATIONS

183. Plaintiffs brings this action on behalf of all individuals and entities who purchased Rain common stock during the Class Period and/or pursuant or traceable to Rain's registration statement filed in conjunction with the Company's initial public offering, and were damaged thereby (the "Class"). Excluded from the Class are Rain, the Individual Defendants and Director Defendants and each of their immediate family members, legal representatives, heirs, successors or assigns, and any entity in which any of the Defendants have or had a controlling interest (the "Class").

184. The Class members are so numerous that joinder of all members is impracticable. Throughout the Class Period, shares of Rain common stock were actively traded on the Nasdaq. While the exact number of Class members is unknown at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other Class members may be identified from records maintained by Rain or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of November 3, 2023, Rain had over 36 million shares of common stock outstanding. Upon information and belief, these shares are held by thousands of individuals located throughout the entire world. Joinder would be highly impracticable.

185. Plaintiff's claims are typical of the claims of the Class members as all Class members are similarly affected by the Defendants' respective wrongful conduct in violation of the federal laws complained of herein.

186. Plaintiffs have and will continue to fairly and adequately protect the interests of the Class members and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

187. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by the Defendants' respective acts as alleged herein;

(b) with respect to the Exchange Act Claims, whether the Defendants acted knowingly or with deliberate recklessness in issuing false and misleading statements concerning Rain's clinical trial plan for milademetan, including the Phase 2 Bypass;

(c) whether the price of Rain's securities during the Class Period was artificially inflated because of the Defendants' conduct complained of herein; and

(d) whether the Class members have sustained damages and, if so, what is the proper measure of damages.

188. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violation of Section 10(b) and Rule 10b-5 Against Rain, Vellanki, and Bryce

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

190. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (2) cause Plaintiffs and other Class members to purchase Rain securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, each of the Defendants took the actions set forth herein.

191. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of Rain securities in an effort to maintain artificially high market prices for Rain securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

192. 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 clinical trial plan for milademetan, including the Phase 2 Bypass.

193. These Defendants employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Rain's value, performance, and continued substantial growth, which included the making of, or participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Rain's clinical trial plan for milademetan under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a

course of business that operated as a fraud and deceit upon the purchasers of Rain's common stock during the Class Period.

194. The Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (1) the Individual Defendants were high-level executives, directors, and/or agents at Rain during the Class Period and members of Rain's management team or had control thereof; (2) each Individual Defendant, by virtue of his responsibilities and activities as a senior officer and/or director of Rain, was privy to and participated in the creation, development and reporting of Rain's SEC filings and public statements concerning Rain's clinical trial plan for milademetan, including the Phase 2 Bypass; (3) each Individual Defendant enjoyed significant personal contact and familiarity with the other Individual Defendants and was advised of and had access to other members of Rain's management team, internal reports, and other data and information about Rain's clinical trial plan for milademetan, at all relevant times; and (4) each Individual Defendant was aware of Rain's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

195. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing risks associated with Rain's clinical trial plan from the investing public and supporting the artificially inflated price of its common stock. As demonstrated by Defendants' misrepresentations concerning the fundamental problems and risks inherent in Rain's Phase 3 MANTRA study throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

196. As a result of the dissemination of materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Rain securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Rain

securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other Class members acquired Rain securities during the Class Period at artificially high prices and were or will be damaged thereby.

197. At the time of said misrepresentations and omissions, Plaintiffs and other Class members were ignorant of their falsity and believed them to be true. Had Plaintiffs and the other Class members and the marketplace known the truth regarding the risks and flaws inherent in Rain's Phase 3 MANTRA study, which were not disclosed by Defendants, Plaintiffs and other Class members would not have purchased Rain securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices that they paid.

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

199. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other Class members suffered damages in connection with their respective purchases and sales of Rain securities during the Class Period.

200. This action was filed within two years of discovery of the fraud and within five years of each plaintiff's purchases of common stock giving rise to the cause of action.

COUNT II

Violation of Section 20(a) of the Exchange Act against Vellanki and Bryce

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

202. The Individual Defendants acted as controlling persons of Rain within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, agency, ownership and contractual rights, and participation in and/or awareness of Rain's operations and/or intimate knowledge of the false information filed by Rain with the SEC and

disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Rain, including the content and dissemination of the various statements that Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of Rain's clinical test criteria, results, reports, press releases, public filings and other statements alleged by Plaintiffs to have been misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

203. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of Rain and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein and exercised the same.

204. As set forth above, Rain and the Individual Defendants each violated Section 10(b), and Rule 10b-5 promulgated thereunder, by their acts and omissions as alleged in this Complaint.

205. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other Class members suffered damages in connection with their purchases of Rain's common stock during the Class Period.

206. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff's purchases of common stock giving rise to the cause of action.

COUNT III

Violation of Section 11 of the Securities Act against Rain and the Director Defendants

207. Plaintiffs specifically disclaim any allegations that are based on fraud, recklessness, or intentional misconduct.

208. This count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of Plaintiffs and other members of the Class against Rain and the Director Defendants.

209. Rain's registration statement and prospectus for the initial public offering was inaccurate and misleading, contained untrue statements of material facts, omitted facts necessary

to make the statements made therein not misleading, and omitted to state material facts required to be stated therein.

210. On April 2, 2021, Rain filed its initial registration statement for the Company's initial public offering. Rain amended the registration statement on April 9 and 19, 2021. On April 23, 2021, Rain filed its final prospectus for the Company's initial public offering, which was incorporated into the registration statement. The final prospectus listed for sale approximately 7.5 million shares of Rain common stock at an offering price of $17 per share.

211. Rain's final prospectus for the initial public offering represented in no less than three separate instances that the trial data from Daiichi Sanyko's Phase 1 trial supported the Company's Phase 2 Bypass. In pertinent part, the prospectus stated as follows:

> Our lead product candidate, RAIN-32 (milademetan, formerly known as DS-3032), is a small molecule, oral inhibitor of mouse double minute 2 (MDM2), which is oncogenic in numerous cancers. We in-licensed RAIN-32 in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors. This trial also ***validated a rationally-designed dosing schedule*** that has been shown to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition, unlocking the potential for RAIN-32 in a broad range of MDM2-dependent cancers. ***Based on these data, we anticipate commencing a pivotal Phase 3 trial in LPS in the second half of 2021*** . . . .

(emphasis added)

212. The statements identified above in emphasis were false and/or materially misleading. Daiichi Sanyko's Phase 1 data did not "validate[]" a "dosing schedule" or support advancing directly to a Phase 3 trial, *i.e.*, Phase 2 Bypass. The Phase 1 trial identified a dose for further testing, *i.e.*, the recommended Phase 2 dose, and therefore had not been "validated" or otherwise "shown to mitigate safety concerns" as represented. Further, the Phase 1 trial did not support a Phase 2 Bypass, which is only appropriate where the drug's mechanism of action and safety profile are well characterized. Milademetan did not meet this standard and, in fact, Daiichi Sankyo itself even intended to conduct a Phase 2 trial to test the dose(s) identified during Phase 1 testing.

213. The Phase 2 Bypass represented an extreme departure from customary practices, industry standards, and widely-accepted academic literature. Rain's prospectus did not disclose

this or otherwise warn of the risks created by the Phase 2 Bypass, as required by Item 105 of Regulation S-K, 17 C.F.R. § 229.105. Item 105 requires in the "Risk Factors" section of registration statements and prospectuses "a discussion of the [most significant] factors that make [the offering] . . . speculative or risky" and requires each risk factor to "adequately describe[] the risk." Rain's registration statement and prospectus warned investors only of generic risks concerning the possibility that results obtained in earlier clinical trials may not be predictive of results in later trials. This warning, without more, was insufficient under Item 105.

214. All clinical trials present a risk of failure. This risk of failure is present even when earlier trials have proved successful. In Rain's case, the Company's clinical trial program presented abnormal, undisclosed, and exceedingly atypical risks given that the Phase 2 Bypass deviated from customary practices, industry standards, and widely-accepted academic literature and even contradicted Daiichi Sankyo's trial plans for a Phase 2 trial, as alleged above. Thus, although Rain warned investors generally that the Phase 3 MANTRA trial could fail, the Company's registration statement and prospectus still failed to inform the public of the most significant factor making its offering speculative and/or risky, which was that the Company was embarking on a clinical trial plan that was unsupported by the Phase 1 data and customary practices, industry standards, and widely-accepted academic literature in light of miladametan's historical safety profile and mechanism of action.

215. Rain is the issuer of the securities purchased by Plaintiffs and other members of the Class. As such, Rain is strictly liable for the materially untrue statements contained in the registration statement and prospectus and their failure to be complete and accurate.

216. The Director Defendants each signed the registration statement filed by Rain for its initial public offering. As such, each is strictly liable for the materially inaccurate statements contained therein and the failure of the registration statement and prospectus to be complete and accurate. The Director Defendants named herein were responsible for the contents and dissemination of the registration statement and prospectus, which were inaccurate and misleading, contained untrue statements of material facts, omitted facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein. The

Director Defendants each had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the registration statement and prospectus and ensure that they were true and accurate and not misleading. In the exercise of reasonable care, the Director Defendants should have known of the material misstatements and omissions contained in the registration statement and prospectus. Accordingly, the Director Defendants are liable to Plaintiffs and the other members of the Class.

217. By reason of the conduct alleged herein, Rain and the Director Defendants violated Section 11 of the Securities Act.

218. Plaintiffs and the other members of the Class acquired Rain common stock pursuant or traceable to the Company's registration statement and prospectus filed in conjunction with the initial public offering and without knowledge of the untruths and/or omissions alleged herein. Plaintiffs and the other members of the Class sustained damages, and the price of Rain's shares declined substantially due to material misstatements in the registration statement and prospectus.

219. This claim was brought within one year after the discovery of the untrue statements and omissions and within three years of the date of the Direct Listing.

220. By virtue of the foregoing, Plaintiffs and the other members of the Class are entitled to damages under Section 11, as measured by the provisions of Section 11(e), from the Defendants and each of them, jointly and severally.

COUNT IV

Violation of Section 15 of the Securities Act against the Director Defendants

221. Plaintiffs repeat and reallege each and every allegation contained in Count III, *supra*. Plaintiffs specifically disclaims any allegations that are based on fraud, recklessness, or intentional misconduct.

222. This Count is brought by Plaintiffs against the Director Defendants pursuant to Section 15 of the Securities Act, 15 U.S.C. § 77o, on behalf of the Class.

223. This Count is asserted against the Director Defendants, each of whom possessed the power to control, and did control, directly and/or indirectly, the actions of Rain at all relevant times.

224. The Director Defendants were each control persons of Rain by virtue of their positions as directors, senior officers, and/or authorized representatives of the Company. The Director Defendants had the power and authority to control the contents of Rain's registration statement and prospectus and had the ability and opportunity to prevent their issuance or cause them to be corrected.

225. As a direct and proximate result of said wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchase of Rain securities.

226. This claim is brought within the applicable statute of limitations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment as follows:

(a) Determining that this action is a proper class action, certifying Plaintiffs as class representative under Federal Rule of Civil Procedure 23 and Plaintiffs' counsel as class counsel;

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

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

In accordance with Fed. R. Civ. P. 38(b), Plaintiffs demand a jury trial of all issues involved, now, or in the future, in this action.

Dated: January 19, 2024

Respectfully submitted,

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