UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____, on behalf of himself and a class of similarly situated investors, Plaintiff, v. SPECTRUM PHARMACEUTICALS, INC., THOMAS J. RIGA, FRANCOIS J. LEBEL, and NORA E. BRENNAN, Defendants.	Civil Action No. JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff _____ ("Plaintiff"), on behalf of himself and a class of similarly situated investors, by and through Plaintiff's counsel, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge.

I. SUMMARY OF THE ACTION

1. This is a securities class action on behalf of all purchasers of Spectrum Pharmaceuticals, Inc. ("Spectrum") common stock during the period December 6, 2021 through September 22, 2022, inclusive (the "Class Period"), who were damaged thereby (the "Class"). The claims asserted herein are alleged against Spectrum, Thomas J. Riga ("Riga"), the Company's President and Chief Executive Officer ("CEO"), Francois J. Lebel ("Lebel"), the Company's Executive Vice President ("EVP") and Chief Medical Officer ("CMO"), and Nora E. Brennan ("Brennan"), the Company's EVP and Chief Financial Officer ("CFO"), and arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

2. Spectrum purports to be a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted oncology therapies.

3. Before the Class Period, Defendants were conducting a Phase 2 clinical trial called ZENITH20. The ZENITH20 trial was an ongoing, multicenter, multi-cohort, open-label, activity-estimating study evaluating the anti-tumor effects, safety, and tolerability of poziotinib, or "pozi", in patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") that have certain mutations (HER2 exon 20 insertion mutations) and were previously treated with the standard of care. Before the Class Period, the Company had a pre-NDA meeting with the FDA, during which Spectrum confirmed with the FDA that Cohort 2 data could serve as the basis of a new drug application ("NDA") submission. In Cohort 2, the objective response rate ("ORR") (complete or partial response, which are measures of whether tumors shrink or are eradicated after treatment) was approximately 28% and the median duration of response was 5.1 months.

4. The HER2 exon 20 insertion mutation occurs in 2-5% of patients with NSCLC. These patients are treated according to the same treatment paradigms as patients with advanced NSCLC without these unique mutations, however, there is an apparent unmet need for these patients because they have a median overall survival ("OS") of 1.6-1.9 years from the time of diagnosis. According to Defendants, if approved, poziotinib could address an unmet need of NSCLC patients previously treated with the standard of care.

5. On December 6, 2021, Spectrum issued a press release announcing it submitted an NDA to the U.S. Food and Drug Administration ("FDA") for poziotinib's use in patients with previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations. The NDA submission was based on purportedly "positive results of Cohort 2 from the ZENITH20 clinical trial, which assessed the safety and efficacy of poziotinib."

6. Defendants were seeking Accelerated Approval ("AA") for poziotinib. The FDA instituted its AA program to allow for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint. For AA, efficacy should demonstrate a meaningful advantage over available therapy. AA allows for earlier access to drugs and biologics based on initial evidence of safety and effectiveness, and requires phase 3 randomized placebo controlled confirmatory studies to verify clinical benefit. If randomized placebo controlled trials completed post-approval verify the clinical benefit of an indication granted AA, then the indication is granted traditional approval.

7. Based on communications with the FDA, Defendants anticipated a decision on its AA application for pozi in November 2022. At the time of an AA, postmarketing requirements ("PMR") are agreed to by the company and FDA. For more than a decade, FDA guidance has provided that confirmatory trials should be ongoing and accruing patients at the time of AA. The FDA "strongly recommends that the confirmatory trial(s) be well underway if not fully enrolled at the time of Accelerated Approval." Confirmatory trials that are in progress at the time of AA are more likely to result in a timely verification of benefit, and mitigate the risks that patients are exposed to undue risks by an ineffective drug.

8. Less than a month after the start of the Class Period, on January 3, 2022, Spectrum entered into a privately negotiated securities purchase agreement with Hanmi Pharmaceutical Co., Ltd. ("Hanmi"), which agreed to purchase 12.5 million shares of Spectrum common stock at $1.60 per share, for an aggregate purchase price of $20,000,000.

9. During the Class Period, Defendants represented the safety and efficacy data from the ZENITH20 trial were positive and that they had initiated the required confirmatory phase 3 study. However, unknown to investors, this was not true.

10. As later revealed to investors, the data submitted by Defendants in support of the NDA failed to show that pozi provided a meaningful advantage over available therapies and therefore was not likely to provide a clinical benefit. During the Class Period, the FDA expressed concerns regarding pozi's safety and efficacy data, and further, the FDA expressed concern that Defendants' phase 3 confirmatory trial, which was required to be substantially enrolled at the time of AA, had not enrolled a single patient during the Class Period. The FDA communicated to Defendants that given the concerns regarding the totality of evidence supporting the NDA, the significant delay in confirming benefit with a randomized trial heightened the uncertainty around the risk benefit assessment of pozi.

11. Starting on September 20, 2022, before the market opened, investors began to learn the truth when the FDA Oncologic Drugs Advisory Committee ("ODAC") released a briefing document in anticipation of its September 22, 2022 meeting with Defendants to review poziotinib. ODAC is an independent panel of experts that reviews and evaluates data concerning the efficacy and safety of marketed and investigational products for use in the treatment of cancer. The committee makes appropriate recommendations to the FDA, but these recommendations are not binding and the final decision regarding product approval will be made solely by the FDA.

12. Investors were surprised when, despite the Company's repeated representations during the Class Period that the data for ZENITH20 were positive, the ODAC briefing document disclosed not only negative data on the safety and efficacy of pozi, but also a failure by the Company to enroll any patients in the required phase 3 confirmatory trial.

13. As a result of this news, shares of Spectrum common stock declined from a closing price of $1.06 per share on September 19, 2022, to a close at $0.66 per share on September 20, 2022, a decline of $0.40 per share, or over 37% on heavier than usual volume.

14. On September 20, 2022, Cantor Fitzgerald issued a report titled "FDA Briefing Docs Negative for Poziotinib Approval" and discussed the concerns raised by the FDA ODAC briefing document concerning pozi, namely: (1) its limited efficacy benefit; (2) safety issues, specifically poor tolerability at the proposed dosage; (3) inadequate dose optimization; and (4) delayed initiation of confirmatory trial. The Cantor Fitzgerald report further noted that shares of Spectrum common stock plummeted 30%, as the FDA briefing documents were very negative for pozi's chances for approval.

15. Also on September 20, 2022, H.C. Wainwright released a report entitled "Upcoming ODAC meeting for pozi could be more argumentative than we initially thought." The H.C. Wainwright report highlighted many of the same concerns as the Cantor Fitzgerald report: "a limited response rate with poor durability, poor tolerability at the proposed dosage, inadequate dosing optimization for efficacy and safety, and delayed initiation of the confirmatory trial." Further, the H.C. Wainwright report noted "the focus on questioning efficacy raises some concerns. Importantly, the confirmatory study of poziotinib 8mg BID has not yet started." As a result of the negative news in the ODAC briefing documents, H.C. Wainwright lowered its probability of success for accelerated approval for pozi.

16. According to *Reuters*, on September 22, 2022, before the opening of the market, trading in Spectrum shares was halted at $0.63 per share pending the outcome of the FDA ODAC meeting.

17. Also on September 22, 2022, ODAC conducted its meeting concerning poziotinib in which Defendant Lebel participated. During the meeting, ODAC voted 9-4 not to recommend poziotinib for AA.

18. On September 23, 2022, trading in Spectrum common stock resumed. As a result

of this news, shares of Spectrum common stock further declined from a closing price of $0.63 per share on September 21, 2022 before trading was halted, to a close at $0.43 per share on September 23, 2022, a decline of $0.20 per share, or over 31% on heavier than usual volume.

19. On September 23, 2022, H.C. Wainwright released a report titled "ODAC Votes Against Poziotinib; Debt Deal Announced; Lower PT by $3". The report noted that the 9 "no" voters from the ODAC cited "non-meaningful benefit over existing therapies and cited dosing issues… Issues related to the Phase 3 confirmatory trial for poziotinib were also raised… as that study has not yet started." The report further stated that "We believe the ODAC vote is negative for potential approval of poziotinib. We note that the FDA does not have to follow the recommendations of the ODAC; however, the FDA's views in the briefing documents and during the meeting do not bode well for approval, in our opinion."

20. Also on September 23, 2022, Jefferies released a report titled "Based on Negative Pozi Adcom, We Anticipate CRL; Next Steps for Pozi Unclear". The report noted "Adcom voted 9-4 that pozi benefits do not outweigh risks. Panel agreed w/ FDA concerns on dosing, lack of confirm trial progress, and that pozi data do not show clear benefit vs SOC." Further, the Jefferies report stated that the "Panel decided evidence on efficacy & unmet need did not outweigh concerns, namely: 1) dosing concerns w/ incongruence b/w 16mg QD dose under review and confirmatory trial's 8mg BID; 2) lack of confirmatory trial progress w/ no pts enrolled as of yet and data likely not until 2026, increasing risk to pts."

21. On November 25, 2022, Defendants caused Spectrum to issue a press release disclosing their receipt of a Complete Response Letter ("CRL") from the FDA regarding Spectrum's NDA for poziotinib. The press release stated the following:

> Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI) ("Spectrum" or the "Company"), a biopharmaceutical company focused on novel

> and targeted oncology therapies, today announced that the Company has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding Spectrum's New Drug Application (NDA) for poziotinib for the treatment of patients with previously treated locally advanced or metastatic non-small cell lung cancer ("NSCLC") harboring HER2 exon 20 insertion mutations. The FDA issued a CRL indicating the poziotinib application cannot be approved in its present form. Based on the CRL, the Company would have to generate additional data including a randomized controlled study prior to approval.
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> "While we are not surprised by the CRL given the ODAC recommendation in September, we are disappointed. After multiple interactions with the FDA since ODAC, and following careful consideration, ***we have made the strategic decision to immediately de-prioritize the poziotinib program***," said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals.

22. As of December 5, 2022, Spectrum stock has not recovered, closing at $0.47 per share.

23. As alleged herein, during the Class Period, Defendants violated the federal securities laws by making false or misleading representations or by failing to disclose material facts they had a duty to disclose.

II. JURISDICTION AND VENUE

24. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by SEC, 17 C.F.R. § 240.10b-5. Jurisdiction for this Court is conferred over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

25. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b). The acts and transactions giving rise to the violations of law complained of occurred in part in this District, including the dissemination of false and misleading statements into this District. In addition, Spectrum's common stock trades on the NASDAQ in this District under the symbol SPPI and Defendants participated in investor

conferences in New York City in this District during the Class Period.

26. In connection with the acts and conduct alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails and interstate wire and telephone communications.

III. PARTIES

27. Plaintiff purchased Spectrum common stock during the Class Period as described in the Certification attached hereto, and suffered damages as a result of the violations of the federal securities laws alleged herein.

28. Defendant Spectrum is a biopharmaceutical company that is incorporated in Delaware, and has its headquarters in Boston, Massachusetts. Spectrum's common stock is traded under the symbol SPPI on the NASDAQ in this District. According to Spectrum's annual report filed with the SEC on March 18, 2022 on Form 10-K ("2021 10-K"), there were 177,151,513 shares of the Company's common stock outstanding as of March 10, 2022.

29. Defendant Riga was appointed the Company's President and CEO and a member of the Company's board of directors effective December 31, 2021. Previously, he served as the Company's Chief Operating Officer since December 2017, as EVP, Chief Commercial Officer and Head of Business Development since May 2017, and as Senior Vice President and Chief Commercial Officer since August 2014. From July 2013 to August 2014, he served as the Vice President, Corporate Accounts. He made materially false and misleading statements and omitted material facts in Spectrum's SEC filings, press releases or on public conference calls with analysts and investors during the Class Period. Defendant Riga, as a senior executive and director of Spectrum, acted within the scope of his authority and as an agent of Spectrum during the Class Period.

30. Defendant Lebel was the Company's EVP and CMO throughout the Class Period.

He made materially false and misleading statements and omitted material facts in Spectrum's SEC filings, press releases or on public conference calls with analysts and investors during the Class Period. Defendant Lebel, as a senior executive of Spectrum, acted within the scope of his authority and as an agent of Spectrum during the Class Period.

31. Defendant Brennan was appointed as the Company's CFO and EVP on May 11, 2022. Prior to being appointed CFO, Defendant Brennan served on Spectrum's Board of Directors and as Chairperson of the Audit Committee since December 2020. She made materially false and misleading statements and omitted material facts in Spectrum's SEC filings, press releases or on public conference calls with analysts and investors during the Class Period. Defendant Brennan, as a senior executive of Spectrum, acted within the scope of her authority and as an agent of Spectrum during the Class Period.

32. Defendants Riga, Lebel, and Brennan, because of their respective positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional and individual investors, *i.e.* the market. They were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected.

IV. DEFENDANTS' FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

33. During the Class Period, Defendants' representations to investors were materially false and misleading at the time they were made, and Defendants failed to disclose material facts that they had a duty to disclose in order to make the statements made by Defendants, in light of the circumstances under which they were made, not misleading.

34. The class period begins on December 6, 2021, when Spectrum issued a press release titled "Spectrum Pharmaceuticals Submits New Drug Application for Poziotinib" that stated the following:

> Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that it has submitted its New Drug Application (NDA) for poziotinib to the U.S. Food and Drug Administration (FDA) for use in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) with HER2 exon 20 insertion mutations. ***The NDA submission is based on the positive results of Cohort 2 from the ZENITH20 clinical trial, which assessed the safety and efficacy of poziotinib.*** The product has received Fast Track designation and there is no treatment specifically approved by the FDA for this indication…
>
> Cohort 2 enrolled 90 patients who received an oral once daily dose of 16 mg of poziotinib. ***The intent-to-treat analysis demonstrated a confirmed objective response rate (ORR) of 27.8% (95% Confidence Interval (CI), 18.9%-38.2%).*** The observed lower bound of 18.9% exceeded the pre-specified lower bound of 17%. ***The median duration of response was 5.1 months*** and the median progression free survival was 5.5 months. In this cohort, 87% of patients had drug interruptions with 11 patients (12%) permanently discontinuing due to adverse events. 13 patients (14%) had treatment-related serious adverse events.

35. On February 11, 2022, Spectrum issued a press release titled "Spectrum Pharmaceuticals Announces Acceptance of New Drug Application Filing for Poziotinib" that stated the following:

> ***The NDA acceptance is based on the positive Phase 2 study results in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations.*** There is currently no treatment specifically approved by the FDA for this indication. The product has received Fast Track designation and the agency has set a Prescription Drug User Fee Act (PDUFA) date of November 24, 2022. ***The FDA reiterated the importance of having the confirmatory trial substantially enrolled at the time of approval and requested additional information around dosing.*** The FDA also indicated that it is not currently planning to hold an advisory committee meeting for the application.

> "The NDA acceptance is a major step toward advancing the treatment for patients with HER2 exon 20 insertion mutations in lung cancer," said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. "This remains an area of high unmet medical need as there are no treatments specifically approved for these patients. We are actively working with the agency to support the review process."
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> About the Phase 2 Study Results (Cohort 2 of ZENITH20 Study)
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> The Phase 2 study enrolled 90 patients who received an oral once daily dose of 16 mg of poziotinib. ***The intent-to-treat analysis demonstrated a confirmed objective response rate (ORR) of 27.8% (95% Confidence Interval (CI), 18.9%-38.2%).*** The observed lower bound of 18.9% exceeded the pre-specified lower bound of 17%. ***The median duration of response was 5.1 months*** and the median progression free survival was 5.5 months. In this cohort, 87% of patients had drug interruptions with 11 patients (12%) permanently discontinuing due to adverse events. 13 patients (14%) had treatment-related serious adverse events.

36. On March 17, 2022, Defendants Riga and Lebel caused Spectrum to issue a press release titled "Spectrum Pharmaceuticals Reports Fourth Quarter 2021 and Full Year 2021 Financial Results and Corporate Update", that stated the following:

> Poziotinib NDA accepted for FDA review in previously treated patients with NSCLC harboring HER2 exon 20 insertion mutations, PDUFA date November 24, 2022
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> ***Positive poziotinib results in treatment naïve patients with NSCLC harboring HER2 exon 20 insertion mutations*** . . .
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> "We have made significant progress against our core business objectives including the acceptance of the poziotinib NDA . . . ***We have also recently released positive data in front-line NSCLC patients harboring HER2 exon 20 insertion mutations***," said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. . . .
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> Pipeline Updates . . . Poziotinib, a Pan ErbB inhibitor targeting HER2 exon20 mutations
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> - The New Drug Application (NDA) was accepted for review by the FDA under a Fast Track designation. ***The NDA is based on the positive results of Cohort 2 in patients with***

> ***previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations.*** The agency has set a Prescription Drug User Fee Act (PDUFA) date of November 24, 2022. There is no FDA approved therapy for patients with NSCLC harboring HER2 exon 20 insertion mutations.

37. On March 17, 2022, after the market closed, Defendants Defendant Riga and Lebel participated in an earnings call with analysts and investors. During that call, an analyst asked about the status of the Company's confirmatory trial for poziotinib. Specifically, the analyst asked, "What do you think the FDA means by substantially enrolled? And what is your confidence that you'll be able to reach cycle by your PDUFA date?" Defendant Lebel responded, in pertinent part:

> So what I can tell you today is that actually, ***we have initiated the confirmatory study***. We secured our first Central IRB approval, and we are operating with a great sense of urgency, to the point you're making, we're very aware that we need to show significant enrollment. The FDA does not define what they mean. And I think, we think that being able to demonstrate good momentum is critical, and that's why we are proceeding and the whole team is proceeding with great urgency as we speak.

38. Also during the March 17, 2022 earnings call with investors, an analyst asked Defendants Riga and Lebel "how should we be thinking about a potential label in second line? Is there the possibility of getting the 8-milligram BID dosing? Or are you thinking it has to be 16-milligram to start?" Defendant Riga responded, in pertinent part:

> So you know that the Cohort 2 was dosed at 16 milligrams QD and through Cohort 5 and a number of the work that we've done have produced a pretty healthy body of evidence in the BID setting. So we'll wait and see until the label negotiation part of the discussion with the agency occurs. ***But we are seeing that 16 QD is certainly a safe and effective dose. And I think over time, we have learned to optimize some of the tolerability and abate some of the AEs here with the BID dosage.*** So I think that will be a key topic when we get to label negotiations with the agency, and we're simply not at that point of the review cycle, which will be coming here shortly."

39. On March 18, 2022, Defendants caused the Company to file the 2021 10-K. The

2021 10-K, which was signed by Defendants Riga and Brennan, represented that "The NDA submission is based on the positive results of Cohort 2 from the ZENITH20 clinical trial, which assessed the safety and efficacy of poziotinib."

40. The 2021 10-K also warned of potential risks relating to the Company's clinical development of poziotinib. The 2021 10-K stated:

> In addition, the company announced the submission of the poziotinib NDA in December 2021. In February of 2022, the company announced that ***the FDA accepted the NDA and reiterated the importance of having the confirmatory trial substantially enrolled at the time of approval and requested additional information around dosing***. Due to the uncertainty of the regulatory approval process, ***we may not*** be successful at developing these drugs or receiving approval.

41. On May 12, 2022, Defendants caused the Company to issue a press release titled "Spectrum Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Corporate Update." The press release stated, in relevant part:

- "In the first quarter, ***we initiated a confirmatory study*** and presented additional positive scientific data for poziotinib."
- "***A study for poziotinib has been initiated to confirm the clinical benefit seen in Cohort 2, as required for an accelerated approval***. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. ***Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally***."
- ***"The NDA is based on the positive results of Cohort 2 in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations."***

42. On May 12, 2022, after the market closed, Spectrum hosted an earnings call with analysts and investors, in which Defendants Riga and Lebel participated. Defendant Lebel provided an update on the status of the ZENITH20 and Phase 3 study for poziotinib and stated the

following:

> "***We now have initiated a randomized confirmatory study following discussion with the FDA and are operat[ing] with a great sense of urgency***. Study SPI-POZ-301 or PINNACLE is designed to enroll 268 patients with previously treated non-small cell lung cancer, harboring HER2 exon 20 mutation. ***Patients are being randomized 2:1 into this global multicenter study to receive 8-milligram of pozi-administered BID versus 75-milligram per meter square of docetaxel-administered IV every 3 weeks***."

43. Also on the May 12, 2022 earnings call, an analyst asked Defendants Riga and Lebel, in reference to the confirmatory trial, "what preparations are you doing? What are you expecting the advisory committee to ask?" Defendant Riga responded, in pertinent part:

> "It's very logical that the FDA ***could*** have additional questions on dosing and wanting to hear from industry experts on how to bring that issue to resolution."

44. Also on the May 12, 2022 earnings call, an analyst asked Defendants Riga and Lebel "how much will we learn from your ongoing studies? And what might be the data you are able to present to the panel on the 8 mg? And how do you reconcile a full approval in a different dose with the [accelerated] approval with a sort of different dosing schedule?" Defendant Riga responded, in relevant part:

> "So the registrational filing is based on cohort 2. As you mentioned, the 16 milligrams given QD, and the PMR [post marketing requirement] is at 8-milligrams BID. So both are 16-milligrams per day. ***We believe that 16-milligrams QD demonstrated a safe and effective dose for a patient population that needs a solution***… So I think that the conundrum that you mentioned is likely a topic that FDA would like to hear from industry experts at the ODAC panel. ***But we believe that 16 QD is a safe and effective dose and obviously aligned with FDA on the confirmatory study to go with the 8-milligram BID***"

45. On May 12, 2022, Defendants caused the Company to file its quarterly report for the quarter ended March 31, 2022 with the SEC on Form 10-Q ("Q1 2022 10-Q"). The Q1 2022 10-Q was signed by Defendant Riga. The Q1 2022 10-Q represented that: "The NDA submission

is based on the positive results of Cohort 2 from the ZENITH20 clinical trial, which assessed the safety and efficacy of poziotinib."

46. The Q1 2022 10-Q also stated that there were "no material changes to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 17, 2022." The 2021 10-K stated the following:

> In addition, the company announced the submission of the poziotinib NDA in December 2021. In February of 2022, the company announced that ***the FDA accepted the NDA and reiterated the importance of having the confirmatory trial substantially enrolled at the time of approval and requested additional information around dosing.*** Due to the uncertainty of the regulatory approval process, ***we may not*** be successful at developing these drugs or receiving approval.

47. On June 16, 2022, Defendants Riga and Lebel participated in the JMP Securities Life Sciences Conference in New York City during which Defendant Riga represented that pozi "has demonstrated efficacy in the second line, previously treated populations with that specific mutation [HER 2 exon 20], which is where the NDA is under active review with FDA."

48. On August 11, 2022, Defendants caused Spectrum to issue a press release titled "Spectrum Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Corporate Update" that stated the following:

> **Pipeline Updates**
>
> **Poziotinib, a Pan ErbB inhibitor targeting HER2 exon 20 mutations**
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> - The New Drug Application (NDA) for poziotinib is under active review at the FDA with Fast Track designation and a PDUFA date of November 24, 2022. ***The NDA is based on the positive results of Cohort 2 from the ZENITH20 clinical trial in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations***. There is currently no EDA approved therapy for patients with NSCLC harboring HER2 exon 20 insertion mutations

- ***A study for poziotinib is in progress to confirm the clinical benefit seen in Cohort 2, as required for accelerated approval***. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. ***Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally administered BID (twice daily) verses 75mg/m2 of docetaxel administered intravenously every three weeks.*** The primary endpoint is progression free survival.

49. On August 12, 2022, Defendants caused the Company to file its quarterly report for the quarter ended June 30, 2022 with SEC on form 10-Q ("Q2 2022 10-Q). The Q2 2022 10-Q, which was signed by Defendant Brennan, represented that: "The NDA submission is based on the positive results of Cohort 2 from the ZENITH20 clinical trial, which assessed the safety and accuracy of poziotinib."

50. The Q2 2022 10-Q also contained warnings of potential risks regarding the clinical development of poziotinib. The Q2 2022 10-Q stated, in pertinent part:

> In addition, the company announced the submission of the poziotinib NDA in December 2021. In February of 2022, the company announced that ***the FDA accepted the NDA and reiterated the importance of having the confirmatory trial substantially enrolled at the time of approval and requested additional information around dosing***. Due to the uncertainty of the regulatory approval process, ***we may not*** be successful at developing these drugs or receiving approval.

51. Defendants' statements alleged in paragraphs 34-50 were materially false and misleading, or omitted to disclose material facts necessary to be disclosed in order to make the statements, in light of the context in which they were made, not misleading because before and during the Class Period, the FDA had raised material, negative concerns with Defendants about the safety and efficacy of pozi, Defendants' dose selection or dose optimization for pozi, and that Defendants had not enrolled a single patient in the required Phase 3. As later revealed, pozi's purportedly positive ORR of 28% in study's 90 patients was illusory. In the Zenith20 trial, for

patients who received other anti-tumor treatment in addition to pozi, the ORR similar was (23%, raising significant doubts about pozi anti-tumor efficacy. Moreover, pozi was poorly tolerated at the 16mg QD (once daily dosage for which the Company was seeking FDA approval, with most patients receiving a reduced dose within one month after treatment initiation, and there were three patient deaths deemed probably or possibility related to pozi. Moreover, the pozi data submitted by Defendants in support of the NDA did not provide a meaningful advantage over available therapies and indicated that pozi was not likely to provide a clinical benefit.

52. In light of these material negative concerns regarding pozi's safety and efficacy data, the FDA expressed concern that Defendants' phase 3 confirmatory trial, which was required to be substantially enrolled at the time of AA, had not enrolled a single patient during the Class Period. The FDA communicated to Defendants that given the concerns regarding the totality of evidence supporting the NDA, the significant delay in confirming benefit with a randomized trial heightened the uncertainty around the risk benefit assessment.

V. THE TRUTH BEGINS TO EMERGE

53. On September 20, 2022, before the market opened, the FDA released a briefing document ahead of its scheduled September 22, 2022 ODAC meeting regarding poziotinib. In sharp contrast to Defendants' representations that the Zenith20 data was positive and that the required confirmatory Phase 3 trial was initiated and patients were being randomized, the briefing document identified material negative concerns about the efficacy and safety data supporting the pozi NDA, and revealed that Defendants' Phase 3 confirmatory trial had not enrolled a single patient.

54. As a result of these disclosures, the price of Spectrum's common stock declined from a closing price on September 19, 2022 of $1.06 per share, to close at $0.66 per share on September 20, 2022, a decrease of $0.40 per share or over 37%, on massive trading volume of

over 21.85 million shares.

55. Then, on September 22, 2022, Defendants caused Spectrum to issue a press release concerning the FDA ODAC's meeting that stated the following:

> **SPECTRUM PHARMACEUTICALS PROVIDES AN UPDATE ON POZIOTINIB FOLLOWING FDA ONCOLOGIC DRUGS ADVISORY COMMITTEE MEETING**
>
> Spectrum Pharmaceuticals (NasdaqGS: SPPI) ("Spectrum" or the "Company"), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that the U.S. Food and Drug Administration's ("FDA") Oncologic Drugs Advisory Committee ("ODAC") met to review poziotinib for the treatment of patients with previously treated locally advanced or metastatic non-small cell lung cancer ("NSCLC") harboring HER2 exon 20 insertion mutations. The committee voted 9-4 that the current benefits of poziotinib did not outweigh its risks.

(Emphasis added.)

56. As a result of this news, shares of Spectrum common stock fell again, from a closing price on September 22, 2022 of $0.63 per share to $0.43 at close on September 23, 2022, a decrease of $0.20 or approximately 31% on heavier than usual volume.

57. On November 25, 2022, Defendants caused the Spectrum to issue a press release disclosing that the Company received a CRL from the FDA indicating the poziotinib NDA cannot be approved in its present form.

VI. LOSS CAUSATION

58. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the prices of Spectrum common stock and operated as a fraud or deceit on purchasers of Spectrum common stock. As detailed above, when the truth about Spectrum's misconduct was revealed, the value of the Company's stock declined precipitously as the prior artificial inflation no longer inflated the stock's prices.

The decline in the price of Spectrum shares was the direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the share price declines negate any inference that the losses suffered by Plaintiff and other members of the Class were caused by changed market conditions, macroeconomic or industry factors, or Company specific facts unrelated to the Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and other Class members, was a direct result of Defendants' fraudulent scheme to artificially inflate the prices of the Company's stock and the subsequent significant decline in the value of the Company's stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

59. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and other Class members. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of the results of the ZENITH20 data and status of the confirmatory study, as alleged herein. Throughout the Class Period, Defendants issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing the prices of Spectrum's common stock to be artificially inflated. Plaintiff and other Class members purchased Spectrum stock at those artificially inflated prices, causing them to suffer damages.

VII. ADDITIONAL SCIENTER ALLEGATIONS

60. During the Class Period, Defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of Spectrum common stock

during the Class Period.

61. Defendants were motivated to commit the acts alleged herein in order to inflate the price of Spectrum common stock and sell it at artificially inflated prices. On January 3, 2022, Spectrum entered into a securities purchase agreement with Hanmi in which Spectrum sold 12.5 million shares of Spectrum common stock at a price equal to $1.60 per share of Common Stock for an aggregate purchase price of $20,000,000. Moreover, both Defendants Riga and Lebel sold shares of Spectrum common stock for proceeds of approximately $100,000, and neither of them purchased any Spectrum shares on the open market.

VIII. NO SAFE HARBOR

62. Spectrum's "Safe Harbor" warnings accompanying any forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

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

64. In addition, the FLS were contradicted by existing, undisclosed material negative facts that were required to be disclosed so that the FLS would not be misleading. Finally, most of the purported "Safe Harbor" warnings were themselves misleading because they warned of "risks"

that had already materialized or failed to provide any meaningful disclosures of the relevant risks.

IX. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

65. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's common stock traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

(e) Plaintiff and other members of the Class purchased Spectrum common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

66. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). Here, the Class' claims are also grounded on Defendants' failure to disclose material adverse information regarding the material, adverse data of the ZENITH20 trial and the efficacy, safety, and dosing optimization of poziotinib, as well as the material adverse information that the FDA had already expressed concerns regarding ZENITH20 and the confirmatory study—information that the Defendants should have disclosed and proof that positive reliance is not a prerequisite to recovery. Instead, the withheld facts must be material in the sense that a reasonable investor may have considered them important in making investment decisions. Based on the alleged omissions

herein, this requirement is satisfied here.

67. At all relevant times, the market for Spectrum common stock was efficient for the following reasons, among others:

(a) As a regulated issuer, Spectrum filed periodic public reports with the SEC;

(b) The Company's shares traded on NASDAQ, an efficient market;

(c) Defendants regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and investors, and other similar reporting services;

(d) The Company was covered by research analysts, including Jefferies, Cantor Fitzgerald, H.C. Wainwright, and B. Riley; and

(e) Spectrum was eligible to file a Form S-3 Registration Statement under the Securities Act of 1933 with the SEC, and, in fact, filed a Registration Statement on Form S-3/A on May 7, 2020.

X. CLASS ACTION ALLEGATIONS

68. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf the Class. Excluded from the Class are Defendants, directors and officers of Spectrum, and their families and affiliates. The members of the Class are so numerous that joinder of all members is impracticable.

69. The disposition of Class members' claims in a class action will provide substantial benefits to the parties and the Court. Spectrum had more than 177 million shares of common stock outstanding as of March 10, 2022 and more than 188 million shares outstanding as of August 8,

2022.

70. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) Whether the Exchange Act was violated by Defendants;

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

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

(d) Whether Defendants knew, or disregarded with at least recklessness, that their statements were false and misleading at the time they were made;

(e) Whether the prices of Spectrum common stock were artificially inflated; and

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

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

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

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

XI. CAUSES OF ACTION

COUNT I

For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

74. Plaintiff incorporates paragraphs 1-73 by reference.

75. During the Class Period, Defendants disseminated or approved the false and misleading statements specified above, which they knew, or disregarded with at least recklessness, were misleading in that they contained misrepresentations or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

76. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Spectrum common stock during the Class Period.

77. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Spectrum common stock. Plaintiff and the Class would not have purchased Spectrum common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

78. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiff

and the other members of the Class suffered damages in connection with their purchases of Spectrum securities during the Class Period.

COUNT II

For Violation of Section 20(a) of the Exchange Act Against Defendants Riga, Lebel, and Brennan

79. Plaintiff incorporates paragraphs 1-73 by reference.

80. Defendants Riga, Lebel and Brennan each acted as a controlling person of Spectrum within the meaning of Section 20 of the Exchange Act. By virtue of their respective positions as senior executives and/or directors of the Company and their power to control public statements to investors about Spectrum, which they exercised throughout the Class Period, Defendants Riga, Lebel and Brennan had the power and ability to control the actions of Spectrum and its employees.

81. By reason of such conduct, Defendants Riga, Lebel and Brennan are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23, certifying Plaintiff as class representative, and appointing Plaintiff's counsel as class counsel;

B. Awarding Plaintiff and the members of the Class damages and interest;

C. Awarding Plaintiff reasonable costs, including attorneys' fees; and

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

JURY DEMAND

Plaintiff demands a trial by jury.