UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. STEFANO R. CARCHEDI, MARIE L. FOEGH RAMWELL, and JAMES G. CULLEM Defendants.	)	Case No. **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff United States Securities and Exchange Commission ("the Commission") alleges:

SUMMARY

1. From February 2020 to February 2022, three senior executives of Massachusetts-based Allarity Therapeutics, Inc. ("Allarity" or the "Company"), Stefano Carchedi, Marie Foegh Ramwell ("Foegh"), and James Cullem (collectively, the "Defendants"), schemed to conceal from investors a harsh critique levied by the Food and Drug Administration ("FDA") about the approval prospects for Allarity's flagship cancer drug candidate, dovitinib. Specifically, in February 2020, the FDA recommended that Allarity *not* submit its proposed drug application seeking approval to market and sell dovitinib, because the data was insufficient, and instead conduct a new drug trial—something Allarity had no intention of doing.

2. Defendants each knew, or were reckless in not knowing, that dovitinib would not be approved for sale to the public absent a new drug trial. Despite that, Defendants hid the

FDA's admonitions from investors and more broadly. In addition, Carchedi propagated false and misleading claims about dovitinib's efficacy and likelihood of approval in Allarity's efforts to raise money from investors to stay afloat.

3. Ultimately, Allarity submitted its flawed drug application to the FDA on December 21, 2021, without conducting a new trial as recommended by the FDA. Allarity's press release announcing the submission of its drug application did not disclose that the FDA had advised against the submission.

4. The same day Allarity submitted its drug application, Allarity announced that it had listed its stock on the NASDAQ stock exchange and secured a $20 million investment from a single investor, largely premised on Allarity having a viable drug application for dovitinib. That investor, like the public, was unaware that dovitinib had virtually no chance of approval absent a new trial.

5. Then, on February 18, 2022, Allarity revealed for the first time a problem with its drug application, announcing that the FDA had refused to even *review* the application—a drastic measure by FDA standards. The next trading day, Allarity's share price closed down approximately 31%.

6. By knowingly, recklessly, or negligently engaging in the conduct described in this Complaint, Carchedi violated Section 17(a) of the Securities Act of 1933 ("Securities Act") and Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 thereunder, and Cullem and Foegh violated Sections 17(a)(1) and (3) of the Securities Act and Section 10(b) of the Exchange Act and Rules 10b-5(a) and (c) thereunder.

7. The Commission seeks (a) a permanent injunction prohibiting the Defendants from directly or indirectly engaging in the conduct described herein, or in conduct of similar purport and effect; (b) disgorgement plus pre-judgment interest; (c) civil penalties; and (d) officer and director bars.

JURISDICTION AND VENUE

8. The Court has jurisdiction over this action pursuant to Sections 20(d) and 22(a) of the Securities Act [15 U.S.C. §§77t(d), 77v(a)], and Sections 21(d), 21(e) and 27 of the Exchange Act [15 U.S.C. §§78u(d), 78u(e), 78aa].

9. Venue is proper in this District because Allarity maintained an office in Massachusetts since at least October 2020 and, at all relevant times, Allarity conducted business in Massachusetts and Cullem lived in Massachusetts. A substantial part of the actions that give rise to the Commission's claims also occurred in Massachusetts.

10. In connection with the acts described in this Complaint, Defendants directly or indirectly made use of the mails or the means or instruments of transportation or communication in interstate commerce.

11. Defendants' conduct involved fraud, deceit, or deliberate or reckless disregard of regulatory requirements, and resulted in substantial loss, or significant risk of substantial loss, to other persons.

DEFENDANTS

12. **Stefano R. Carchedi ("Carchedi")**, age 63, was the chief executive officer, the president, and a board member for Allarity or its predecessor from September 2019 to June 2022,

when he was terminated for conduct related to the allegations in this Complaint. Before joining Allarity, Carchedi worked in various senior positions, including as CEO, for numerous pharmaceutical companies since 1989. Currently, he serves as chairman of the board for a privately held manufacturer of laboratory equipment for the life sciences industry. Carchedi is a resident of Lower Gwynedd, Pennsylvania.

13. **Marie L. Foegh Ramwell ("Foegh")**, age 82, was the chief medical officer of Allarity or its predecessor from May 2017 to March 2024. She is presently employed as a physician in Denmark and as an independent pharmaceutical consultant and expert witness. She also currently serves as chairman of the board of a Danish pharmaceutical packaging company. She is licensed as a medical doctor in the District of Columbia, Maryland, and Virginia. Foegh is a resident of New York, New York, East Patchogue, New York and Denmark.

14. **James G. Cullem ("Cullem")**, age 56, was Allarity's chief executive officer from June 2022 to December 2023. He was also the chief business officer from December 2021 to June 2022, the senior vice president of corporate development from October 2019 to December 2021, and a board member from June 2022 to January 2024 for Allarity and/or its predecessor. Presently, he runs his own consulting firm to the life sciences industry. He is a licensed attorney in Massachusetts and a resident of Newburyport, Massachusetts.

RELEVANT ENTITY

15. **Allarity Therapeutics, Inc.**, ("Allarity"), a Delaware corporation, is a small biopharmaceutical company whose principal place of business is in Boston, Massachusetts. From at least October 2020 to the present, Allarity maintained a U.S. office in Massachusetts. Before October 2020, Allarity maintained a U.S. office in Scottsdale, Arizona. Allarity's

common stock is registered with the Commission under Section 12(b) of the Exchange Act and has traded on the NASDAQ stock exchange under the symbol "ALLR" since December 21, 2021. Prior to incorporating in Delaware and registering its stock with the Commission, Allarity was a Danish company and operated under the names Oncology Venture A/S and Allarity Therapeutics A/S, both of which traded on a Swedish stock exchange.

STATEMENT OF FACTS

The FDA Approval Process

16. Before a drug can be marketed and sold in the U.S., a drug company must obtain approval from the FDA. According to the FDA, it will only approve a drug if it is safe and there is "substantial evidence" consisting of "adequate and well-controlled" trials demonstrating that the drug is effective for its intended use in humans.

17. To demonstrate the safety and efficacy of a drug, pharmaceutical companies conduct human clinical trials in three phases. Phase III trials, the largest and most expensive of the three phases, are supposed to provide sufficient evidence of efficacy and safety to enable the FDA to evaluate the overall risk-benefit relationship of the drug.

18. Drug trials can be "superiority" trials (which seek to demonstrate that the test drug is *more* effective than the comparison drug) or "non-inferiority" trials (which seek to demonstrate that the efficacy of the test drug is within a clinically acceptable margin (the "non-inferiority margin") of the efficacy of the comparison drug). Per published FDA guidance, this "non-inferiority margin" must be specified before the trial begins to avoid the potential bias created by already knowing the trial results when the non-inferiority margin is set.

19. Typically, clinical trials for cancer drugs, like dovitinib, measure efficacy in terms of (1) overall survival ("OS") (the length of time from the start of treatment to patient death) or (2) progression-free survival ("PFS") (the length of time from the start of treatment to the earlier of tumor growth or patient death). Assessing tumor growth, and thus PFS, requires more subjectivity on the part of the investigator than OS; consequently, FDA guidance states that OS is the optimal endpoint.

20. If a pharmaceutical company believes it has generated sufficient evidence of safety and efficacy, it may seek approval to market and sell its drug to the public. It does so by submitting a New Drug Application ("NDA") to the FDA.

21. Within 60 days of a company submitting an NDA, the FDA must either "file" the NDA, meaning the FDA deems it sufficiently complete to permit a substantive review, or issue a Refusal to File ("RTF") letter. An RTF letter is typically reserved for circumstances where the NDA is incomplete, because it does not on its face contain certain required information, or where the required content is presented in an unusable form. An RTF also may be warranted when a single trial underpins a submitted NDA, but the FDA has advised the drug company previously that more than one trial would be required.

Dovitinib's Success was Material to Allarity

22. Allarity is a biopharmaceutical company focused on pairing cancer drug candidates that have been abandoned or shelved by other companies with a genetic test Allarity developed, thus targeting patients most likely to benefit from a particular cancer drug. One such drug candidate was dovitinib.

23. Dovitinib originally was developed by another pharmaceutical company, Company A, for the treatment of advanced renal cell carcinoma, a particularly deadly form of kidney cancer. Company A ceased developing dovitinib after a 2013 Phase III trial failed to show that dovitinib was more effective than (or superior to) a comparator drug ("the Dovitinib Trial"). In 2018, Allarity licensed dovitinib from Company A.

24. Dovitinib's hoped-for approval by the FDA was material to Allarity because the company had yet to have a drug approved for sale to the public. As a result, at all relevant times, the estimated likelihood of dovitinib's success factored heavily into Allarity's business prospects. As Allarity itself acknowledged in 2021 public filings with the Commission, "[i]f we are unable to submit an NDA to the U.S. FDA for our therapeutic candidate dovitinib… or if we experience significant delays in doing so," or "[i]f we are unable to… receive marketing approval for… dovitinib…our business could be substantially harmed."

Allarity is Admonished by the FDA

25. In December 2019, Allarity requested a meeting with FDA staff to discuss Allarity's analysis of the Dovitinib Trial data and the anticipated filing of the dovitinib NDA (the "FDA Meeting").

26. In correspondence ahead of the FDA Meeting, Allarity communicated to the FDA its plan to rely on a retrospective, non-inferiority analysis of PFS from the Dovitinib Trial and solicited the FDA's feedback on various questions. Although this plan contravened published FDA guidance, Allarity chose to rely on a *non-inferiority* analysis of PFS because the Dovitinib Trial had already failed to show dovitinib was *superior* to the comparator drug on either PFS or OS.

27. The FDA staff responded in writing on February 14, 2020, saying in the preamble of the written comments: "We do not agree with your plan to submit an NDA based on a retrospective non-inferiority analysis of a trial that failed to demonstrate superiority. There are multiple issues with your proposal..." The specific issues the FDA noted were Allarity's proposal to 1) define the non-inferiority margin for its analysis *after* the Dovitinib Trial had already concluded and 2) analyze PFS rather than OS. The FDA took issue with Allarity's analysis because it was susceptible to manipulation for two reasons: one, Allarity was proposing to define the non-inferiority margin for its analysis *after* it already knew the results of the Dovitinib Trial; and two, Allarity was planning to assess the more subjective of the two study endpoints, PFS (rather than OS).

28. In responding to Allarity's question, "Does the Agency agree that the proposed clinical data supporting the proposed safety and efficacy claims are adequate to support the submission of the NDA for the proposed indication?" the FDA responded, "No," and referenced the preamble again. In response to another Allarity question, "Does the Agency agree that this statistical approach is adequate to support the filing of dovitinib in the proposed indication?" the FDA also responded, "No."

29. For all eleven written questions posed by Allarity to the FDA, the FDA referenced back to the preamble in their responses, putting Allarity on notice that the FDA was highly unlikely to even accept the dovitinib NDA for substantive review, much less approve it.

30. Carchedi, Foegh and Cullem each received a copy of the FDA's written response on February 14, 2020.

31. The next day, Allarity's Chief Science Officer emailed Carchedi and Foegh to

note that the FDA's published guidance referenced in the FDA's written response to Allarity appeared to be an "insurmountable hurdle" because it prohibited the exact analysis Allarity planned to use as the basis for the dovitinib NDA.

32. On February 20, 2020, Allarity and FDA staff met in person. Carchedi and Foegh attended the FDA Meeting along with various consultants Allarity had retained to advise it on its regulatory strategy.

33. The official minutes of the FDA Meeting, which were created by FDA staff during the meeting, with Allarity employees and consultants present, summarized the parties' main discussion points. The minutes stated, in relevant part, "FDA reiterated that unplanned determination of non-inferiority following failure to show superiority would not suffice for demonstrating non-inferiority of dovitinib and that PFS is not an appropriate endpoint for a non-inferiority trial. The FDA recommended that [Allarity] prospectively plan and conduct a new trial"—the strongest language the FDA uses in meeting minutes.

34. Foegh, Carchedi, and Cullem each received a copy of the official meeting minutes on March 18, 2020. In an email to an Allarity consultant, Foegh described the minutes as "pretty negative in terms of filing" with "[n]early every answer to our questions [beginning] with Do not file the NDA."

35. Allarity's consultants who attended the FDA Meeting took notes of their own. These notes also reflected the grim outcome of the FDA Meeting. One set of notes memorialized that:

a. "FDA essentially claimed that there was simply no efficacy (or, insufficient efficacy) with dovitinib"
b. "sounded like FDA doesn't want to see dovitinib get on the market,"
c. "Several different times, and in different ways, FDA reiterated that the 'non-

inferiority approach'…was invalid….FDA further stated that the 'use' of PFS and the definition of disease progression was invalid for / impossible to use with an NI approach."

d. "the possible submission of an NDA was 'delaying the inevitable.'"

Foegh and Cullem received a copy of these notes on February 20, 2020, and February 22, 2020, respectively.

36. A different consultant's notes observed that:

a. "FDA reiterated its position that the trial that the NDA is based upon did not *demonstrate superiority and that [Allarity] cannot now use the data and apply it to non*-inferiority trial." [emphasis in original],
b. "the [FDA] is asking [Allarity] not to submit the NDA," and
c. "FDA stated that they do not currently advise submitting an application[.]"

Carchedi and Foegh received these notes on or about March 11, 2020.

Defendants Schemed to Hide the FDA's Recommendations

37. Allarity issued a press release on March 20, 2020, purporting to update the public, including investors, on the outcome of the FDA Meeting. Carchedi, Foegh and Cullem helped draft the press release, and Carchedi approved it. The press release remained on Allarity's public website through at least 2022.

38. This press release painted a wholly inaccurate and incomplete picture of the FDA Meeting. One, it falsely claimed, "FDA indicated that they would accept the [New Drug Application] filing if submitted, and provided additional guidance regarding the submission[.]" In actuality, Defendants knew, or were reckless in not knowing, the FDA had recommended *against* submitting the dovitinib NDA and had threatened not to accept it for filing.

39. Two, the press release represented that: "[Allarity] plans to use the data from the [Dovitinib Trial] to prove that Dovitinib is in fact 'non-inferior' to [the comparison drug] for the treatment of [renal cell carcinoma], and expects that Dovitinib will be approved by the FDA as a

safe and efficacious drug[.]" This statement was false and misleading because Defendants knew, or were reckless in not knowing, that the FDA had outright rejected this plan and that dovitinib would not be approved on such data.

40. Three, the press release stated that the FDA has "provided input on the 'non-inferiority' margin" and "discussed progression free survival (PFS) as an endpoint for 'non-inferiority,'" but misleadingly omitted FDA's *actual* input— i.e., that Allarity's proposed analysis was invalid and unusable.

41. Finally, the March 20, 2020, press release was misleading because it did not disclose the crux of the FDA's feedback—the recommendation that Allarity conduct a new trial prior to submitting its NDA. By omitting this information, Defendants misrepresented the strength of the dovitinib NDA and its likelihood of approval.

42. Carchedi, Cullem and Foegh also misled Allarity's Board of Directors. On March 30, 2020, only twelve days after Defendants received a copy of the strident FDA meeting minutes, Allarity's Board met.

43. Carchedi presented at the Board meeting. According to the Board minutes, Carchedi falsely characterized the FDA Meeting as "positive"— withholding from the Board the FDA's admonishment not to submit the dovitinib NDA and instead conduct a new trial. Cullem also attended the Board meeting as secretary, but did not disagree with Carchedi's characterization or disclose the FDA's actual feedback to the Board.

44. Defendants were all regular presenters at Board meetings thereafter. However, at no point before filing the dovitinib NDA in December 2021 did any of the Defendants alert the Board to the FDA's forceful criticisms, despite dovitinib's undeniable importance to Allarity's

business prospects.

45. Defendants' deception also extended to Company A, from which it had licensed dovitinib and which had signed a non-disclosure agreement with Allarity. On February 16, 2021, Company A requested a copy of the FDA Meeting minutes. Rather than provide Company A with an unadulterated copy of the minutes pursuant to the non-disclosure agreement in place, Carchedi and Cullem undertook to redact any negative information from the minutes. When Cullem circulated the proposed redactions internally on March 5, 2021, he explained, "I have redacted (blackout text) any of the FDA comments about unwillingness to accept non-inferiority etc." Cullem then sent Company A the heavily redacted version of the minutes on March 18, 2021, copying Foegh.

46. On August 23, 2021 and November 23, 2021, Allarity published on its website two "Interim reports," one of which it also filed with the SEC, for the purpose of disclosing information about its proposed move from Denmark to the U.S. and the exchange of shares traded on the Swedish stock exchange for shares that would trade on the NASDAQ. Carchedi helped draft, and signed, both reports.

47. In the Interim reports, Allarity misrepresented that the FDA Meeting "provided guidance to the Company regarding its potential path to approval" and "[b]ased on this feedback from the FDA, Allarity plans to file a New Drug Application ("NDA") for the approval of dovitinib . . . during 2021" (emphasis added). This was misleading because the FDA's feedback had been *not* to submit the dovitinib NDA but instead to conduct a new trial.

48. The interim reports also misrepresented dovitinib as having "shown identical clinical activity to [the comparator drug]" in the Dovitinib Trial. This claim was misleading for

three reasons: 1) Allarity's post-hoc, non-inferiority analysis of the Dovitinib Trial did not even assess whether dovitinib had "identical clinical activity" to the comparator drug —a more exacting standard than non-inferiority; 2) it omitted that the Dovitinib Trial had failed to show dovitinib was *superior* to the comparator drug on either PFS or OS; and 3) it neglected to disclose that the FDA had rejected Allarity's proposal to use the Dovitinib Trial to demonstrate dovitinib's efficacy.

49. In anticipation of listing Allarity stock on NASDAQ, on November 4, 2021, Allarity filed with the Commission a Form S-4 Registration Statement containing a prospectus. On December 16, 2021, Allarity filed with the Commission a Form S-1 Registration Statement containing a prospectus in connection with a $20 million investment from an investor, allowing that investor to offer and sell the Allarity shares it would receive in exchange for its investment in Allarity. Carchedi signed both prospectuses.

50. Both prospectuses touted dovitinib's purported "therapeutic equivalence to" the already-approved comparison drug and claimed the Dovitinib Trial had "established that dovitinib is non-inferior to [the comparison drug] with respect to PFS and OS." This was misleading because Defendants knew, or were reckless in not knowing, that the FDA disagreed with these efficacy claims.

51. Further, the December 16 prospectus provided the false assurance that "we anticipate…approval of our [NDA]." Defendants knew, or were reckless in not knowing, that the dovitinib NDA would <u>not</u> be approved absent a new trial because the FDA had previously told Allarity that it did not agree with Allarity's plan to submit an NDA based on a retrospective non-inferiority analysis of the Dovitinib Trial. This same prospectus also listed the FDA's

requirements for drug approval based on retrospective analyses, but misleadingly failed to mention that the FDA had told Allarity that the proposed dovitinib NDA had not met such requirements.

52. Throughout 2021, Allarity maintained and periodically updated a slide deck that Carchedi used in discussions with investors and prospective investors. The Defendants each participated in preparing the deck. In this slide deck, which was posted to Allarity's website and filed with the Commission as an exhibit to Form 8-K on January 18, 2022, Allarity falsely claimed dovitinib's efficacy had been demonstrated in a Phase III trial. This was false and misleading because the FDA expressly advised Allarity that the Dovitinib Trial could not be used to demonstrate dovitinib's efficacy for purposes of approval.

53. The slide deck also misleadingly touted that the dovitinib NDA had selected renal cell carcinoma as the lead indication ". . . for **fastest path to approval**" (emphasis in original) of the dovitinib NDA, but omitted the FDA's recommendation not to submit the dovitinib NDA at all and to instead conduct a new trial.

54. Allarity provided a copy of the slide deck to a prospective investor in March 2021, and to at least two prospective investors in October 2021. Allarity ultimately raised $20 million in December 2021 from a single investor in connection with these prospectuses and slide decks.

Defendants Capitalize on the NDA Submission

55. On December 21, 2021, Allarity submitted its NDA for dovitinib. The NDA did not contain data from any second trial, as recommended by the FDA, and was premised on an after-the-fact, non-inferiority analysis of the Dovitinib Trial, which the FDA had warned Allarity

against using. Nevertheless, the press release Allarity issued on December 22, 2021, heralding the milestone did not disclose the FDA's prior criticisms of the data, its admonishment not to submit the NDA, or its recommendation to conduct a new trial. Carchedi gave the final approval on this press release.

56. Also on December 21, 2021, Allarity announced that it had secured $20 million in funding from a single investor and that its stock had begun trading on NASDAQ.

57. For meeting certain goals, including submitting the dovitinib NDA and listing Allarity's stock on the NASDAQ by the end of 2021, the Allarity Board awarded Carchedi a cash bonus of approximately $225,000, Foegh a cash bonus of approximately $132,000, and Cullem a cash bonus of approximately $119,000. All three also received stock option awards.

Defendants' Scheme Unravels

58. On January 27, 2022, FDA staff and Allarity met by phone. Foegh participated in the call. Referring back to its statements from the FDA Meeting, FDA staff again advised Allarity that the dovitinib NDA was riddled with issues—each of which would render it unapprovable—and recommended Allarity withdraw the NDA. Allarity did not withdraw its NDA, but never disclosed to investors that the FDA had recommended withdrawal. Carchedi and Cullem were informed of the outcome of the call later the same day.

59. Then, on February 15, 2022, the FDA issued Allarity an RTF letter. According to the letter, FDA declined to proceed with a substantive review of the dovitinib NDA because a retrospective, non-inferiority analysis of a failed superiority trial cannot be used to demonstrate PFS—the same warning the FDA had communicated to Allarity years before, at the in-person FDA Meeting in 2020.

60. When Allarity's Chairman of the Board received a copy of the RTF letter, on or about February 18, 2022, he emailed Cullem saying, "I'm interested to know who advised us to file against the crystal clear advice of the FDA." Cullem and Carchedi explained in response that securing the $20 million investment in December 2021 had been crucial to Allarity avoiding bankruptcy and filing the NDA had been crucial to the investor providing funding.

61. On February 18, 2022, Allarity, for the first time, publicly revealed a problem with its NDA, announcing its receipt of the RTF letter. The press release, which was drafted, in part, by Carchedi and Cullem and approved by Carchedi, again concealed from investors that the FDA had threatened Allarity with this very outcome years before, in 2020.

62. The next trading day the market reacted strongly, with Allarity's stock price closing down approximately 31%—the largest one-day drop in the stock's history up to that point.

63. Then, in August 2022, Allarity announced it was no longer pursuing development of dovitinib as a stand-alone treatment for kidney cancer.

FIRST CLAIM
Fraud in the Purchase or Sale of Securities in Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Thereunder (Against Carchedi)

64. The Commission repeats and incorporates by reference the allegations in paragraphs 1- 63 above as if set forth fully herein.

65. Carchedi engaged in a fraudulent course of conduct that included making material misrepresentations and omitting to state material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading regarding an FDA

recommendation not to submit an NDA for dovitinib.

66. By engaging in the conduct described above, Carchedi, directly or indirectly, acting knowingly or recklessly, by the use of means or instrumentalities of interstate commerce or of the mails, in connection with the purchase or sale of securities, has employed devices, schemes or artifices to defraud; made untrue statements of material fact or omitted to state material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading; and engaged in acts, practices or courses of business which operate as a fraud or deceit upon certain persons.

67. By reason of the forgoing, Carchedi violated Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5].

SECOND CLAIM
Fraud in the Offer or Sale of Securities in Violation of Section 17(a) of the Securities Act (Against Carchedi)

68. The Commission repeats and incorporates by reference the allegations in paragraphs 1-63 above as if set forth fully herein.

69. Carchedi engaged in a fraudulent course of conduct that included making material misrepresentations and omitting to state material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading regarding an FDA recommendation not to submit an NDA for dovitinib.

70. By engaging in the conduct described above, Carchedi, directly or indirectly, acting knowingly, recklessly, or negligently, in the offer or sale of securities by the use of means or instrumentalities of interstate commerce or the mails, has employed devices, schemes or

artifices to defraud; obtained money or property by means of untrue statements of material fact or the omission of a material fact necessary in order to make the statements, in light of the circumstances under which they were made, not misleading; and engaged in transactions, practices or courses of business which operate as a fraud or deceit upon purchasers of the securities.

71. By reason of the forgoing, Carchedi violated Section 17(a) of the Securities Act [15 U.S.C. §77q(a)].

THIRD CLAIM
Fraud in the Offer or Sale of Securities in Violation of Sections 17(a)(1) and (3) of the Securities Act (Against Cullem and Foegh)

72. The Commission repeats and incorporates by reference the allegations in paragraphs 1-63 above as if set forth fully herein.

73. Cullem and Foegh engaged in a fraudulent course of conduct regarding an FDA recommendation not to submit an NDA for dovitinib.

74. By engaging in the conduct described above, Cullem and Foegh, directly or indirectly, acting knowingly, recklessly, or negligently, in the offer or sale of securities by the use of means or instrumentalities of interstate commerce or the mails, have employed devices, schemes or artifices to defraud; and engaged in transactions, practices or courses of business which operate as a fraud or deceit upon purchasers of the securities.

75. By reason of the forgoing, Cullem and Foegh violated Sections 17(a)(1) and (3) of the Securities Act [15 U.S.C. §77q(a)(1) and (3)].

FOURTH CLAIM
Fraud in the Purchase or Sale of Securities in
Violation of Section 10(b) of the Exchange Act and Rules 10b-5(a) and (c) Thereunder
(Against Cullem and Foegh)

76. The Commission repeats and incorporates by reference the allegations in paragraphs 1-63 above as if set forth fully herein.

77. Cullem and Foegh engaged in a fraudulent course of conduct regarding an FDA recommendation not to submit an NDA for dovitinib.

78. By engaging in the conduct described above, Cullem and Foegh, directly or indirectly, acting knowingly or recklessly, in connection with the purchase or sale of securities, by the use of means and instrumentalities of interstate commerce, or of the mails, or of a national securities exchange have employed devices, schemes or artifices to defraud and have engaged in acts, practices or courses of business which operate as a fraud or deceit upon certain persons.

79. By reason of the forgoing, Cullem and Foegh violated Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rules 10b-5(a) and (c) thereunder [17 C.F.R. §240.10b-5(a) and (c)].

PRAYER FOR RELIEF

WHEREFORE, the Commission requests that this Court:

A. Enter a permanent injunction restraining Defendants and each of their agents, servants, employees and attorneys and those persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, including facsimile transmission or overnight delivery service, from directly or indirectly engaging in the conduct described above, or in conduct of similar purport and effect;

B. Require Defendants to disgorge their ill-gotten gains, plus pre-judgment interest;

C. Require Defendants to pay an appropriate civil monetary penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. §77t(d)], and Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)];

D. Impose an officer and director bar against Defendants pursuant to Section 20(e) of the Securities Act [15 U.S.C. §77t(e)] and Section 21(d)(2) of the Exchange Act [15 U.S.C. § 78u(d)(2)];

E. Retain jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and

F. Award such other and further relief as the Court deems just and proper.

Respectfully submitted,

SECURITIES AND EXCHANGE COMMISSION
By its attorneys,

/s/ *Susan R. Cooke*
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DATED: March 12, 2025

CERTIFICATE OF SERVICE

I, Susan Cooke, hereby certify that this document was filed on this date through the ECF system and will be sent to the registered participants as identified on the Notice of Electronic Filing (NEF) as of the date of this filing.

/s/ Susan R. Cooke

Dated: March 12, 2025