

Fourth Circuit Issues Decisive Opinion Affirming Dismissal of Securities Class Action Against MacroGenics

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Biotech companies are often faced with a dilemma – they need to raise capital to develop novel therapies, and in doing so, they often express honest optimism about interim and topline results from their drugs in development. But they cannot be reasonably expected to disclose all results or interpretations of the clinical data to avoid the threat of shareholder litigation. The US Court of Appeals for the Fourth Circuit recently published an opinion that thoughtfully recognized the difficulties that biotech companies face in disclosing the results of clinical trials, emphasizing that such companies should not be punished for expressing optimism, and that investors should know that not every known fact would necessarily support a company's opinions. The court also made clear that courts are not an arbiter of science, and "securities law is simply not a vehicle through which courts will police disagreements in the cancer research community or the parameters of clinical trials."

Summary

On March 2, 2023, the Fourth Circuit affirmed the US District Court for the District of Maryland's complete dismissal of a putative securities class action accusing MacroGenics and several executives of misleading investors about interim clinical trial data.

The plaintiffs' core theory was that the company misled investors by disclosing some positive clinical trial data, while not disclosing purportedly negative data from the same study.

The court rejected the plaintiffs' theory, holding that:

- Disclosure of certain endpoint data and general references to topline results did not trigger a duty to disclose data for all endpoints of the study.
- The defendants' interpretation of clinical trial data amounted to an inactionable opinion statement. The plaintiffs' disagreement with that interpretation was insufficient to state a securities fraud claim.
- Certain positive statements about the clinical trial's survival endpoint were inactionable statements of corporate optimism.

Importantly, the court emphasized that biopharmaceutical companies should not be punished for expressing optimism and that investors should know that not every known fact would necessarily support a company's opinions:

*"Biopharmaceutical clinical trial drug companies constantly find themselves in the hot seat. Not only does their longevity depend on the creation of ground-breaking, experimental drugs designed to combat the world's deadliest illnesses, i.e. Cancer, but also a significant portion of their success turns on the amount of capital raised to explore these uncharted waters, making investors an integral part of the equation. **Therefore, we cannot admonish these companies for issuing positive and accurate opinions while 'weighing ... competing facts,' and must remind investors to 'not expect that every fact known to an issuer supports its opinion statement'** (emphasis added). It would be a great disservice to stifle biopharmaceutical companies' pursuit of medical advancements by failing to safeguard against an inundation of lawsuits alleging securities-law violations."*

Background

MacroGenics is a biopharmaceutical company that, during the relevant time period, was developing an antibody treatment for metastatic breast cancer known as margetuximab. MacroGenics carried out a Phase 3 trial designed to compare the drug's efficacy to the standard of care antigen. The Phase 3 trial's two endpoints were (1) prolongation of progression

free survival (PFS), which measured how long patients continued to survive without the disease getting worse, and (2) prolongation of overall survival (OS), which measured how long patients survived after treatment (regardless of disease progression). The goal of the trial was to demonstrate that margetuximab had “meaningfully superior” PFS and OS results compared to the standard of care.

In February 2019, MacroGenics issued a press release disclosing that the Phase 3 trial had reached its first PFS endpoint. The press release also stated that “follow-up ... on the ... primary endpoint of overall survival (OS) is ongoing.” On a conference call the same day, MacroGenics’ CEO stated that “the trending for OS has been positive in the direction of margetuximab, but we just don’t have enough events to be able to have significance here.”

A few days later, the company announced a public offering and filed a prospectus supplement, which contained various risk factors relating to the Phase 3 trial’s topline results and endpoints.

In May 2019, the company issued a press release disclosing interim OS data from a subset of patients. The company described these interim results as “promising,” and stated that “we anticipate the preliminary positive trend in favor of argetuximab to continue, although subsequent results could fluctuate as additional events accrue.”

At a June 2019 conference, the company disclosed a Kaplan-Meier curves graph depicting the interim OS data from the Phase 3 trial. The plaintiffs alleged that this graph contained materially adverse information that had not been previously disclosed – namely, that the curves in the graph indicated the OS data was not on track to demonstrate superior OS results to the standard of care. After the conference, MacroGenics’ stock declined 22%.

In September 2019, the plaintiffs brought a securities class action alleging claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Sections 11, 12(a) and 15 of the Securities Act of 1933. The district court dismissed the plaintiffs’ claims for failure to plead falsity and scienter, and the plaintiffs appealed.

The decision

The Fourth Circuit affirmed the district court’s dismissal, holding that the plaintiffs failed to adequately plead that any challenged statement was false or misleading when made.

No duty to disclose interim results

The Fourth Circuit held that the defendants did not have a duty to disclose the interim OS results because their statements regarding the PFS endpoint did not speak to the OS data.

- The court explained that the February 2019 press release focused on the PFS endpoint and made clear that the OS data was ongoing and preliminary. Importantly, the defendants’ reference to the OS data in the press release did not put the interim data “in play.” The court explained that “**a company’s mere reference to full trial data in a discussion of top-line results ‘does not trigger a duty to disclose the full results of a study’**” (emphasis added).
- Further, neither did the defendants’ oral statements positively characterizing the OS data put it “in play.” The court observed that the plaintiffs were not challenging the OS interim data itself, but the **defendants’ interpretation** of it. The court emphasized that the plaintiffs’ **different interpretation** was insufficient to plead falsity and explained that “here a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study.” Because the defendants’ statements about the OS data were consistent with the Kaplan-Meier curves graph, and they had “accurately interpreted the OS interim data,” their positive statements about the data were not false or misleading.

Inactionable puffery

The Fourth Circuit held that MacroGenics’ statements regarding the OS data were merely corporate optimism, and its use of the words “positive,” “excited” and “promising” were “textbook examples of puffing statements that reasonable investors cannot rely upon in the hopes of a grand slam, when the bases aren’t even fully loaded.” For example, the plaintiffs challenged the following statements:

- “The **trending for OS has been positive** in the direction of margetuximab.” (emphasis added)
- “The activity observed to date in is **promising**.” (emphasis added)
- “For , we anticipate the preliminary positive trend ... to continue.”

After determining these statements were puffery, the court observed that the statements were “consistently qualified ... with warnings that the OS endpoint could still fail,” citing examples such as “follow up ... is ongoing,” “we just don’t have enough events ... to have significance here,” and “it is too early to evaluate the ... primary endpoint of” The court concluded that the defendants’ statements were “hedged with guarded and restrained positivity,” and as a whole, investors would not have “exclusively clung” to them.

Inactionable opinion

The court also held that the company’s positive statements about the interim OS data were inactionable opinions. The court found that the plaintiffs’ allegations regarding the Kaplan-Meier graph were simply a disagreement with the company’s interpretation of the OS data. The court explained that “interpretations of clinical trial data are considered opinions,” and **“securities law is simply not a vehicle through which courts will police disagreements in the cancer research community or the parameters of clinical trials”** (emphasis added). Because the defendants’ interpretation was accurate and consistent with the later-disclosed Kaplan-Meier graph, and the plaintiffs had “failed to sufficiently allege that Defendants did not believe their general positivity and enthusiasm about the results of the interim OS data,” the court concluded that “the mere fact that Plaintiffs interpreted the data in the graph differently does not make Defendants’ statements actionable.”

Forward-looking statements

The court further held that MacroGenics’ statement **anticipating** “the preliminary positive trend in favor of argetuximab **to continue**” (emphasis added) was forward-looking and protected by the Private Securities Litigation Reform Act safe harbor. The court explained the statement was a projection of future performance because it articulated the company’s expectation that the OS data would continue to show longevity. Notably, the court held that though the statement used the word “continue” (which references “a state that is currently occurring”), it was not a statement of present fact because, in context, it could not be “meaningfully distinguished from” the defendants’ goals of meeting the OS endpoint.

Cautionary statements

Finally, the Fourth Circuit rejected the plaintiffs’ argument that MacroGenics’ risk warnings were actionable because they omitted the Kaplan-Meier graph. The court found that the defendants sufficiently warned investors that the interim OS data was not final and the endpoint may not be met, citing examples of risk factors, including:

- “the topline results may result in the final data being materially different from the preliminary data we previously published ... the achievement of one primary endpoint for a trial does not guarantee that additional co-primary endpoints or secondary endpoints will be achieved.”
- “the achievement by margetuximab of its co-primary endpoint for events in the trial does not indicate whether the co-primary endpoint of will be achieved.”

Takeaways

- The court acknowledged the challenge that clinical-stage biopharmaceutical companies face in deciding what clinical trial data to disclose and not disclose under federal securities laws. Biopharmaceutical companies should not be punished for expressing optimism about clinical development and data, even where some data may cut against their opinions. Holding otherwise would stifle innovation.
- Passing references to topline results and statements regarding particular endpoints do not trigger a duty to disclose **all** study data, particularly where there are risk disclosures warning investors that achievement of one endpoint does not guarantee achievement of other endpoints, and that the results are subject to change. The case provides a good example of risk disclosures a court has found sufficiently strong to warn investors that topline results of interim data are subject to change.
- Statements containing general, positive references to topline results can be considered inactionable puffery, particularly where coupled with risk warnings.
- The Fourth Circuit has joined other circuits in finding that interpretation of clinical data is opinion and has stated unequivocally that courts should not serve as arbiters of science.
- This case demonstrates the importance of accurately disclosing trial data. It was significant to the court’s analysis that the Kaplan-Meier graph was consistent with the company’s earlier comments about the interim OS data, and that the company’s interpretation and depiction of the OS data was “accurate.”
- Statements containing present-tense words like “continue” may be considered forward-looking when read in their full context; however, this is a fact-specific inquiry, the outcome of which may vary.

Employees' Retirement System of the City of Baton Rouge and Parish of East Baton Rouge v. MacroGenics, Inc., No. 21-2238, 2023 WL 2320351, at *9 (4th Cir. March 2, 2023).

Id. at *10.

Id. at *11.

Id. at *12 (citing *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 174 (3d Cir. 2014)).

Id.

Id. at *13.

Id.

See *In re Rigel Pharmaceuticals, Inc. Securities Litigation*, 697 F.3d 869, 878 (9th Cir. 2012); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170–71 (3d Cir. 2014) (“interpretations of clinical trial data are considered opinions.”); *Tongue v. Sanofi*, 816 F.3d 199, 213-14 (2d Cir. 2016) (“Plaintiffs’ allegations regarding Defendants’ stated opinion about the trial results are little more than a dispute about the proper interpretation of data”); *Kleinman v. Elan Corporation, PLC*, 706 F.3d 145, 154 (2d Cir. 2013) (“Defendants are not required to adopt view regarding the degree of difference or its effect on the results.”).

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