

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND

SATISH SHAH  
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:  
v. : Civil Action No. DKC 12-0341  
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GENVEC, INC., et al. :  
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**MEMORANDUM OPINION**

Presently pending and ready for resolution in this putative securities fraud class action is a motion to dismiss filed by Defendants GenVec, Inc., and corporate officers Paul H. Fischer, Douglas J. Swirsky, and Mark O. Thornton. (ECF No. 21). The issues are fully briefed and the court now rules pursuant to Local Rule 105.6, no hearing being deemed necessary. For the reasons that follow, the motion will be granted.

**I. Background**

On July 6, 2012, Plaintiffs Rob Ferry, Robert T. Schiff, Donald A. Schumer, Scott Sheckler, and Anne Vandelanotte, individually and on behalf of all purchasers of GenVec, Inc., common stock between March 12, 2009, and March 29, 2010 ("the class period"), filed an amended complaint alleging violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5, 17

C.F.R. § 240.10b-5. (ECF No. 20).<sup>1</sup> The following facts are drawn from the amended complaint and documents incorporated by reference therein.<sup>2</sup>

**A. Factual Background**

**1. Events Prior to the Class Period**

GenVec is a small clinical stage biopharmaceutical company based in Gaithersburg, Maryland, specializing in the development of novel therapeutic drugs and vaccines. At all times relevant, its lead therapeutic product candidate was "TNFerade™ biologic" ("TNFerade"), a drug that showed early promise in clinical trials for the treatment of cancer. (*Id.* at ¶ 3). "TNFerade is an adenovector, or DNA carrier, which contains the gene for tumor necrosis factor-alpha ('TNF alpha'), an immune system

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<sup>1</sup> The plaintiff identified in the caption, Satish Shah, was named in the original complaint, but not the amended pleading. Because the amended complaint names multiple plaintiffs, they are collectively referred to herein as "Plaintiffs."

<sup>2</sup> In the context of securities fraud litigation, facts outside the complaint may be considered where the "complaint quotes selectively from various reports by investment analysts" and the plaintiff does not "challenge the authenticity of the analyst reports attached to defendants' motion to dismiss and cited in plaintiffs' complaint." *Cozzarelli v. Inspire Pharms., Inc.*, 549 F.3d 618, 625 (4<sup>th</sup> Cir. 2008). Indeed, "district courts in this circuit 'routinely take judicial notice of newspaper articles, analysts' reports, and press releases in order to assess what the market knew at particular points in time, even where the materials were not specifically referenced in the complaint.'" *In re Human Genome Sciences Inc. Sec. Litig.*, --- F.Supp.2d ----, ----, 2013 WL 1223344, at \*5 (D.Md. Mar. 26, 2013) (quoting *Johnson v. Pozen Inc.*, No. 7:07CV599, 2009 WL 426235, at \*5 (M.D.N.C. Feb. 19, 2009)).

protein with potent and well-documented anti-cancer effects, for direct injection into tumors." (*Id.* at ¶ 42). Once injected, "TNFerade works by causing cells in the tumor to produce and secrete [TNF alpha]," which "binds to cells in the tumor, leading to the death of cells in the tumor." (*Id.* at ¶ 67). By locally delivering protein to cells, GenVec's core technology had the added advantage of "reduc[ing] side effects typically associated with systemic delivery of proteins." (*Id.* at ¶ 41).

Before any new drug can be marketed, it must first be approved by the Food and Drug Administration ("FDA"). As Plaintiffs acknowledge, the process of gaining FDA approval is decidedly rigorous:

It takes on average 12 years and over \$700 million to get a new drug from molecule to market. Once a company develops a drug, it generally undergoes years of laboratory testing before an application is made to the FDA to begin testing the drug on humans. Only approximately one in 1,000 of the compounds that enter laboratory testing will ever reach human testing. Only 8% of drugs that enter Phase I clinical trials are eventually approved by the FDA.

(*Id.* at ¶ 38).

Among the drugs that are ultimately approved for human testing, "clinical trial programs for a pharmaceutical product consist of three sequential phases of clinical trials, which can overlap":

Phase 1 trials are the first stage of testing the drug in human subjects. This phase is designed to assess the safety, tolerability, pharmacokinetics (what the body does to the drug), and pharmacodynamics (what the drug does to the body) of a drug on a small group of subjects. Once the initial safety of the drug has been confirmed through Phase 1 trials, the second phase of testing is performed, usually on larger groups, and designed to assess how well the drug works, as well as to continue safety assessments. Data from a Phase [2] clinical trial or trials are normally used to design the third and final phase of clinical trials. A dose effect, increased effectiveness with increased dose, is considered evidence of efficacy by the FDA, and dose comparisons are a specified form of controlled trials in FDA regulations. The third and final phase of clinical trials normally proceeds only if the Phase [2] trial or trials provide adequate evidence of efficacy and safety of a pharmaceutical product.

(*Id.* at 39).

TNFERade was approved for testing on human subjects and performed well in two separate Phase 1 trials. As GenVec reported in 2004, "TNFERade, in conjunction with standard radiation therapy, demonstrated that it was generally well tolerated" and "tumor size reduction of 25% or greater was observed in more than 70% of patients in 12 different tumor types, including pancreatic, rectal, melanoma, small cell lung, breast, and sarcoma." (*Id.* at ¶ 44). Based on those results, GenVec "initiated a Phase 2, dose-escalation study in 50 patients with locally advanced pancreatic cancer to determine

the best therapeutic dose of TNFerade in combination with standard chemoradiation." (*Id.* at ¶ 45). The results of that testing also showed "an apparent dose related improvement in survival." (*Id.*).

GenVec next "initiated a randomized, controlled, Phase 2 study of 74 patients," which, "[i]n consultation with the FDA, . . . was amended in March 2006 to become a Phase 2/3, 330-patient pivotal [Pancreatic Cancer Clinical Trial ("PACT Trial")] that would support registration of TNFerade for this indication." (*Id.*). As Plaintiffs describe it:

The PACT Trial [was] a study for the treatment of unresectable, locally advanced pancreatic carcinoma that included a comparison of: 1) treatment using TNFerade plus standard of care therapy; and 2) treatment using only standard of care therapy. Standard of care therapy consisted of 5 ½-weeks of concurrent radiation therapy 5 days weekly and fluorouracil by continuous infusion 5 days weekly followed, approximately four weeks after completion of chemoradiation, by patients receiving gemcitabine or gemcitabine/erlotinib maintenance therapy. The primary endpoint for the PACT Trial was originally based on 12-month survival.

(*Id.*). GenVec "reported the preliminary analysis of safety data based on the first 40 patients treated and survival data on the first 51 patients treated" in December 2006. (*Id.* at ¶ 46). The safety analysis "indicated that there was no significant difference in the occurrence of serious adverse events

(including thrombotic events) between the treatment and control groups" and the efficacy data showed "a potentially emerging trend of an overall survival advantage in patients receiving TNFerade." (*Id.*).

In January 2008, GenVec reached an agreement with the FDA to change the primary efficacy endpoint of the trial from twelve-month survival to overall survival, which the company reported "could be considered a basis for full regulatory approval of TNFerade for this indication." (*Id.* at ¶ 47). The agreement further contemplated that both GenVec and an independent Data Safety Monitoring Board ("DSMB") would conduct interim analyses of the PACT Trial at two specific points - namely, "following one-third (92) and two-thirds (184) of the total events (deaths) for the study, with the potential to stop the trial for futility or if there was clear evidence of the drug's efficacy." (*Id.*).<sup>3</sup> In other words, the study was to be "unblinded," *i.e.*, data was to be collected and examined, only after the deaths of 92 trial participants ("the first interim

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<sup>3</sup> Data safety monitoring boards "are responsible for ensuring the safety of patients participating in clinical trials and for monitoring such trials for possible early termination due to excessive risks." *In re Pfizer, Inc. Sec. Litig.*, Nos. 04 Civ. 9866 (LTS)(JLC), 05 md 1688 (LTS), 2010 WL 1047618, at \*5 (S.D.N.Y. Mar. 22, 2010); *see also Bonds v. Leavitt*, 629 F.3d 369, 374 (4<sup>th</sup> Cir. 2011) (a DSMB is "tasked with protecting study participants' interests").

analysis") and again after the deaths of 184 trial participants ("the second interim analysis").

On November 19, 2008, GenVec issued a press release announcing survival data from the first interim analysis of the PACT Trial. The press release stated, in relevant part:

Interim data demonstrated an approximately 25% lower risk of death in the TNFerade plus standard of care (SOC) arm relative to the SOC alone (Hazard Ratio=0.753;<sup>[4]</sup> 95% Confidence Interval [0.494-1.15]<sup>[5]</sup>). An independent Data Safety Monitoring Board reviewed the interim analysis data and recommended the trial continue as planned.

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<sup>4</sup> The press release defined the term "hazard ratio" as "an estimate of the treatment effect in the treated versus the control group in a trial." (ECF No. 21-22, at 6). GenVec explained, "[t]he hazard ratio reported means that, at the time of the interim analysis, a TNFerade patient had 0.75 times the chance of dying compared to someone in the standard of care group." (*Id.*).

<sup>5</sup> The "confidence interval" is "a limit above or below or a range around the sample mean, beyond which the true population is unlikely to fall." *Perez v. Mountaire Farms, Inc.*, 650 F.3d 350, 362 (4<sup>th</sup> Cir. 2011) (citing D. Barnes & J. Conley, *Statistical Evidence in Litigation*, § 3.15 at 107 (1986)). It is, "in simple terms, the 'margin of error.'" *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litig.*, 524 F.Supp.2d 1166, 1174 (N.D.Cal. 2007).

With regard to the confidence interval at issue here, Plaintiffs do not challenge Defendants' interpretation that "the [f]irst [i]nterim [a]nalysis suggested that, once the full PACT study was concluded, patients receiving TNFerade would have shown a risk of death between roughly 51% lower than patients on [standard of care] ([i.e.], a highly effective treatment) and 15% higher than patients on [standard of care] (i.e., an ineffective treatment)." (ECF No. 21-1, at 10-11 n. 32).

Kaplan-Meier analysis of data, based on this interim analysis, demonstrated that overall survival at 12 months was 39.9% in the TNFerade plus SOC arm versus 22.5% in the SOC arm. Overall survival at 18 months was 30.5% in the TNFerade plus SOC arm versus 11.3% in the SOC arm. At 24 months, overall survival was 10.6% in the TNFerade plus SOC arm versus 11.3% in the SOC arm. Median survival was 9.9 months in both arms of the trial.

"Successfully passing this milestone in the PACT trial represents an important step forward in the clinical development of TNFerade," stated Mark Thornton, M.D., Ph.D., Senior Vice President of Product Development at GenVec. Thornton continued, "We believe these data are encouraging and justify moving forward with the trial. The continuation of the trial will allow the data to mature and provide for future analyses. We currently estimate we will reach the required number of events needed to conduct the next analysis of data in the PACT study in late 2009."

The next interim analysis will be conducted after 184 deaths have occurred (two-thirds of total expected events) in the PACT trial. "At our current rate of enrollment we also anticipate having enrolled over 300 out of 330 total patients planned for the trial by the end of next year," added Thornton.

(ECF No. 21-22, at 5). In the same press release, GenVec announced that "TNFerade has been granted Fast Track product designation by the U.S. Food and Drug Administration (FDA) for

its proposed use in the treatment of locally advanced pancreatic cancer." (*Id.* at 6).<sup>6</sup>

While GenVec "called the first interim analysis of the PACT Trial 'encouraging,' certain efficacy data presented in the November 19, 2008[,] press release was troubling, raising doubts about the drug." (ECF No. 20 ¶ 53). Indeed, these doubts were reflected in the NASDAQ Global Market, as "the Company's stock declined from a close of \$11.50 on November 18, 2008[,] to a close of \$6.50 on November 19, 2008[,] reaching a low of \$3.80 on November 25, 2008." (*Id.* at ¶ 54). As one analyst

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<sup>6</sup> Regarding "Fast Track" product designation, the United States Court of Appeals for the D.C. Circuit explained:

The FDA has several [] regulatory programs designed to hasten research of the safety and effectiveness of drugs for terminally or severely ill patients and allow early access where scientifically and medically warranted. For example, under its "Fast Track" program, the agency has "established procedures designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely-debilitating illnesses, especially where no satisfactory alternative therapy exists." 21 C.F.R. § 312.80. Fast Track allows the FDA to waive its [investigational new drug] application requirement if it is "unnecessary or cannot be achieved," *id.* § 312.10, and even allows a waiver request to be made "[i]n an emergency . . . by telephone or other rapid communication," *id.*

*Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 699 n. 4 (D.C. Cir. 2007) (en banc).

summarized in a November 19, 2008, article posted on *TheStreet.com*:

GenVec (GNVC) shares sank Wednesday despite what the company said was a positive update on its experimental pancreatic cancer drug TNFerade.

Patients with pancreatic cancer treated with TNFerade plus a standard of care demonstrated a 25% lower risk of death than similar patients treated with standard of care alone, according to an interim analysis of a phase III study released by GenVec on Wednesday.

GenVec executives called these results encouraging and said the TNFerade study will continue. On the surface, the data do look positive. After all, pancreatic cancer is very difficult to treat, so if TNFerade is reducing the risk of death, there's reason for optimism.

Yet, GenVec shares sank [] after the company released the new data and held a conference call. Some potential concerns pop up once a deeper look is taken of the interim TNFerade results.

The 25% lower risk of death attributed to TNFerade corresponds to a "hazard ratio" of 0.75, according to the GenVec interim analysis.

. . . .

The problem that GenVec may run into, however, is that the interim hazard ratio is likely to increase as this study matures, with more patients enrolled and more patients dying.

The interim analysis Wednesday was conducted after the 92nd patient in the study died. The next interim analysis will be conducted

after the 184th death, expected in late 2009. When that second interim analysis occurs, my guess is that the 25% reduction in the risk of death observed Wednesday will shrink considerably.

This is not just an off-the-cuff prediction. Other TNFerade data announced by GenVec Wednesday provides enough evidence to be wary about the drug's chances for success.

At 12 months, 39.9% of TNFerade-treated patients were alive compared to 22.5% of patients in the study's control arm. At 18 months, overall survival for TNFerade was 30.5% compared to 11.3% in the control arm. Both analyses favor TNFerade.

However, at 24 months, only 10.6% of patients treated with TNFerade were still alive compared to 11.3% of patients in the control arm. In other words, the benefit of TNFerade vanished.

Moreover, median survival in the study to date was 9.9 months for both TNFerade and the control arms. No difference.

(ECF No. 21-34, at 2).

Plaintiffs allege that, despite GenVec's publically-stated optimism for the first interim analysis results, its corporate officers, privately, took a much dimmer view. In support of these allegations, they rely largely on the reports of a number of confidential witnesses ("CWs"), former GenVec employees who gave statements on condition of anonymity, regarding internal meetings at around the time the results first became known.

CW1, "a Clinical Trial Assistant from May 2008 until February 2009" (ECF No. 20 ¶ 156), attended a November 2008

clinical staff meeting during which "[D]efendant Thornton revealed the interim TNFerade results [and] . . . used a set of graphs to explain [them]" (*id.* at ¶ 161). "CW1 stated that all [of] the attendees of the meeting understood that the results were not good news because the numbers were marginal." (*Id.*). CW1 was also present at an "all-employee meeting in November 2008" where the first interim results were discussed. (*Id.*). "CW6, a Senior Regulatory Affairs Associate from 2006 until January 2009," attended the all-employee meeting and "saw charts presented by [D]efendant Thornton that showed that the distance between the standard of care and the standard of care [plus] TNFerade was not much[.]" (*Id.* at ¶ 164). Similarly, CW3, "a Senior Analytical Associate working on the TNFerade program from March 2004 until January 2009" (*id.* at ¶ 157), "had done development work on TNFerade" and "did not see any significant difference between the standard of care and the standard of care with TNFerade, which s/he and [his or her] colleagues discussed following the meeting." (*Id.* at ¶ 163).<sup>7</sup>

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<sup>7</sup> At least some of the reports of one CW cited by Plaintiffs conflict with other facts alleged in the complaint and documentary evidence incorporated by reference therein. Specifically, according to CW6, "in early January 2009, there [was] an Emergency DSMB (Data Safety Monitoring Board) meeting" following "an email message [that] had gone out to employees that the 184 goal (targeted number of deaths) had been reached." (ECF No. 20 ¶ 165). CW6 further reported that, "before recruitment had reached its goal of 330 patients, the targeted number of deaths was reached (in early January 2009) and that is

In January 2009, GenVec laid off twenty-two employees (from its total workforce of 123 employees). (*Id.* at ¶ 154). CW1 was purportedly told by "one of the full time [Clinical Research Assistants,] . . . that TNFerade was not working and that was the real reason for the lay[]offs that occurred." (*Id.* at ¶ 162). Similarly, CW3 was advised by "her/his boss . . . that the results from the TNFerade were bad and that was the reason for the lay[]offs." (*Id.*). GenVec reported to investors, however, that the layoffs were merely one of a number of "steps to lower [] operating costs" in order to limit expenditures "not critical to the clinical development of TNFerade." (ECF No. 21-5, at 17).

## **2. Events during the Class Period**

The class period set forth in the amended complaint - *i.e.*, March 12, 2009, to March 29, 2010 - encompasses the time from approximately four months after the first interim analysis

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when GenVec decided to 'pull the plug' on the PACT Trial." (*Id.* at ¶ 164). These statements are at odds with every other account in the complaint and the documentary evidence, which reflect that the 184<sup>th</sup> death, triggering the second interim analysis, occurred in January 2010, not 2009. (*Id.* at ¶ 114). Moreover, the complaint reflects that CW6's employment was terminated in January 2009; thus, he or she could have had no credible basis of knowledge as to events occurring internally at GenVec in 2010. "When the bare allegations of the complaint conflict with any exhibits or other documents, whether attached or adopted by reference, the exhibits or documents prevail." *See Fare Deals, Ltd. v. World Choice Travel.com, Inc.*, 180 F.Supp.2d 678, 683 (D.Md. 2001). Accordingly, these allegations will not be considered.

results were announced to the announcement of the second interim analysis results. During this period, Defendants were continuing to enroll patients in the PACT Trial in an effort to reach the total number of trial participants; awaiting the 184<sup>th</sup> death of a trial participant, which would trigger the second interim analysis; and actively engaging in efforts to raise capital.

GenVec's fundraising efforts were necessary, at least ostensibly, to prepare for regulatory approval of TNFerade. As it reported in a March 31, 2009, SEC Form 10-Q filing:

Significant additional capital will be required to develop our product candidates through clinical development, manufacturing, and commercialization, including the continued advancement of TNFerade through the pivotal trial for locally advanced pancreatic cancer, the FDA regulatory review process for TNFerade and the establishment of manufacturing capabilities for TNFerade. We may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, collaborative arrangements, or some combination of these financing alternatives. The current domestic and global economic conditions have made it more difficult for companies like us to access capital from the financial and credit markets, and have made it more likely we will have to pursue additional strategic alliances, licensing arrangements or collaborations for our product candidates, including TNFerade.

(ECF No. 20 ¶ 77).

On May 28, 2009, GenVec issued a prospectus supplement, "which offered up to 9,615,385 shares of the Company's common stock, including the related preferred share purchase rights, and warrants to purchase up to 9,615,385 shares of the common stock." (*Id.* at ¶ 79). By another prospectus supplement issued on August 27, 2009, GenVec "offered up to 8,000,000 shares of the Company's common stock, including the related preferred share purchase rights, and warrants to purchase up to 4,000,000 shares of the common stock." (*Id.* at ¶ 95).

The market's reaction to these offerings was initially tepid. In fact, GenVec announced in an SEC Form 8-K filing dated September 16, 2009, that it had

[r]eceived a notice from The [NASDAQ] Stock Market stating that the minimum bid price of the Company's common stock was below \$1.00 per share for 30 consecutive business days and that the Company was therefore not in compliance with the minimum bid price requirement for continued listing set forth in Marketplace Rule 5450.

. . . .

If the Company does not regain compliance by March 15, 2010, [NASDAQ] will provide written notification to the Company that the Company's common stock will be delisted.

(*Id.* at ¶ 102).<sup>8</sup>

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<sup>8</sup> One court explained the concepts of "bid price" and "ask price" as follows:

The company's fortunes took a turn for the better in November 2009, however, when the FDA granted "orphan drug designation to TNFerade for the treatment of pancreatic cancer." (*Id.* at ¶ 104).<sup>9</sup> As reported in a November 4, 2009, article in the *Washington Business Journal*:

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[NASDAQ] market makers publicize the prices at which they are willing to buy or sell a stock by entering those "quotes" for display on the [NASDAQ] computerized quotation system. The price at which a market maker is willing to buy a security is called its "bid" or "bid price." The price at which a market maker is willing to sell a security is called its "ask" or "ask price" (or its "offer" or "offer price"). Each market maker must simultaneously quote both a bid and an offer price.

*United States v. Alex Brown & Sons, Inc.*, No. 96 CIV 5313 (RWS), 1997 WL 314390, at \*10 (S.D.N.Y. Apr. 24, 1997). "A Company that has its Primary Equity Security listed on the [NASDAQ] Global Market must continue to substantially meet all of the requirements set forth in Rule 5450(a)" by maintaining a "[m]inimum bid price of \$1 per share" and "[a]t least 400 Total Holders." See NASDAQ Manual, Rule 5450(a), available at [http://nasdaq.cchwallstreet.com/NASDAQTools/PlatformViewer.asp?s\\_electednode=chp%5F1%5F1%5F4%5F3&manual=%2Fnasdaq%2Fmain%2Fnasdaq%2Dequityrules%2F](http://nasdaq.cchwallstreet.com/NASDAQTools/PlatformViewer.asp?s_electednode=chp%5F1%5F1%5F4%5F3&manual=%2Fnasdaq%2Fmain%2Fnasdaq%2Dequityrules%2F) (last viewed Sept. 17, 2013).

<sup>9</sup> In *In re NeoPharm, Inc. Sec. Litig.*, 705 F.Supp.2d 946, 950 (N.D.Ill. 2010), the United States District Court for the Northern District of Illinois discussed the significance of orphan drug designation:

The Orphan Drug Act, codified at 21 U.S.C. § 360aa *et seq.*, provides incentives to companies to develop and market drugs for rare diseases - ones affecting fewer than 200,000 people in the United States, or "for which there is no reasonable expectation that the cost of developing and making the

The Gaithersburg-based biotech said Wednesday that the FDA had granted orphan drug designation to TNFerade for the treatment of pancreatic cancer. Orphan drug designation provides potential financial and regulatory incentives including study design assistance, waiver of user fees, tax credits, and up to seven years of market exclusivity upon marketing approval.

The FDA grants orphan drug designation to drugs that may provide a significant therapeutic advantage over existing treatments and target conditions effecting 200,000 or fewer U.S. patients per year.

"Orphan drug designation is a critical step for the development of TNFerade," said GenVec CEO Dr. Paul Fischer. "The designation will strengthen the TNFerade program at GenVec by offering potential clinical development and commercialization benefits," Fischer said.

Investors appeared to agree with Fischer that orphan drug designation was a significant development for GenVec. The company's shares (NASDAQ: GNVC) rose as much as 21 cents, 26 percent, to \$1.01<sup>[10]</sup> in the Wednesday morning trade.

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drug available for treatment in the United States would be recovered from the sales - by designating certain drugs as "orphan drugs." *Alliance Sec. Prods. v. Fleming Co.*, 471 F.Supp.2d 452, 458 (S.D.N.Y. 2007). "The 'orphan drug' designation, intended to encourage research and development of treatments for rare diseases, grants a seven-year marketing exclusion (or monopoly) to the first drug to gain FDA approval." *SEC v. Selden*, 632 F.Supp.2d 91, 94 (D.Mass. 2009).

<sup>10</sup> This number appears to refer to the minimum bid price for GenVec stock. There is no dispute that, on November 4, 2009,

(*Id.* at ¶ 104). A Reuters article published on the same date quoted one market analyst, who recommended GenVec stock in the wake of the orphan drug designation:

“When combined with the unmet medical need for these various indications, the overall market potential quickly becomes meaningful as well as attractive to a potential partner for TNFerade,” Merriman Curhan Ford analyst Joe Pantginis said in a note. Pantginis, who has a “buy” rating on the stock, said the company’s shares have the potential to trade toward a range of \$2.50 to \$3.50.

(*Id.* at ¶ 105). Indeed, the company was able to reestablish compliance with NASDAQ listing requirements, as it announced in an SEC Form 8-K filing and attached press release, dated January 7, 2010. (*Id.* at ¶ 113).

On January 15, 2010, GenVec announced that the 184<sup>th</sup> death had occurred in the PACT Trial, thereby triggering the second interim analysis. The company issued a press release, stating, in relevant part:

This event, which represents two-thirds of the total events expected in the trial, triggers the next interim analysis of overall survival in the trial. GenVec expects data from this interim analysis to be available in approximately 10-12 weeks.

“This is another significant milestone for the PACT trial. The data released at the last interim look were encouraging and we are looking forward to the top-line results

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GenVec was trading at around \$9.00 per share. (See ECF No. 20 ¶ 199; ECF No. 21-33, at 7).

of the upcoming data analysis," stated Dr. Mark Thornton, GenVec's Senior Vice President of Product Development.

The first interim analysis of overall survival in the PACT trial was released in November 2008. These data demonstrated an approximately 25% lower risk of death in the TNFerade plus standard of care arm relative to standard of care alone. . . .

(*Id.* at ¶ 114).

Less than two weeks later, GenVec issued another stock offering of "up to 14,000,000 shares of . . . common stock, including the related preferred share purchase rights, and warrants to purchase up to 4,200,000 shares of the common stock." (*Id.* at ¶ 117). It announced that it would "use the net proceeds from the [o]ffering [over \$26 million] to complete the development of the Company's lead clinical program, [TNFerade] through the filing of a Biological License Application for TNFerade's use in locally advanced pancreatic cancer, and other general corporate purposes." (*Id.* at ¶ 121).

The market reacted skeptically. As reported in a January 27, 2010, article posted on *TheStreet.com*:

Shares of GenVec (GNVC) are down 23% after the tiny drug maker said it had sold 14 million shares of stock and another 4.2 million warrants, raising net proceeds of \$26.2 million. . . . The stock closed Tuesday at \$2.47. In recent trading, shares were down to \$1.88. . . . Now, the \$26 million dollar question is whether Wednesday's financing implies anything about the upcoming interim analysis of the phase

III study of TNFerade in pancreatic cancer. Is GenVec simply being opportunistic about raising money ahead of this important, potentially stock-moving event? Or, is the company fearful that the TNFerade results will be negative, so it's getting the money now while it can? No one but GenVec knows the answer, of course, and the executives aren't about to tell us.

(*Id.* at ¶ 119).

On February 11, 2010, GenVec again issued a stock offering of "up to 150,000,000 [shares] in total of the Company's common stock, shares of preferred stock, and warrants to purchase shares of the common stock, and any combination of the common stock, preferred stock or warrants." (*Id.* at ¶ 123). The supplemental prospectus stated, in part, that "GenVec expects data from th[e] [second interim] analysis to be available in March or April of 2010." (*Id.*).

The second interim analysis results became available, as expected, in late March 2010, and the news was not good. As reported by GenVec on March 29, 2010, the final day of the class period,

[t]he interim data demonstrated an approximately 8% lower risk of death in the TNFerade plus [standard of care] arm relative to the [standard of care] alone (hazard ratio = 0.921; 95% Confidence Interval [0.678 - 1.252]). Accordingly, these data strongly suggest the trial will not achieve the statistical significance required to form the basis for approval of a biological license application in the

population chosen for study, thereby warranting discontinuing the trial.

(*Id.* at ¶ 134).

In the wake of this announcement, GenVec's "stock price plunged \$20.10 per share - from \$28.10 per share on March 29, 2010[,] to close to \$8.00 per share on March 30, 2010 - a decline of more than 71.5% on unusually high volume." (*Id.* at ¶ 138). This lawsuit followed.

#### **B. Procedural History**

Former plaintiff Satish Shah commenced the action by filing the original complaint on February 3, 2012. On April 3, 2012, the current plaintiffs, calling themselves "the GenVec Investor Group," filed a motion for appointment as lead plaintiffs and for approval of the law firm of Brower Piven, PC, as lead counsel. That motion was granted.

On July 20, 2012, prior to any response by Defendants to the original pleading, Plaintiffs filed their amended complaint. (ECF No. 20). Defendants moved to dismiss on September 4, 2012 (ECF No. 21); Plaintiffs filed opposition papers on November 12, 2012 (ECF No. 24); and Defendants replied on December 20, 2012 (ECF No. 25).<sup>11</sup>

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<sup>11</sup> On February 7, 2013, Plaintiffs filed a motion to strike a portion of Defendants' reply memorandum. (ECF No. 26). Plaintiffs do not indicate the legal basis of this motion, but the only candidate is Federal Rule of Civil Procedure 12(f), which allows the court to strike certain matters "from a

## II. Standard of Review

The purpose of a motion to dismiss under Rule 12(b)(6) is to test the sufficiency of the complaint. *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4<sup>th</sup> Cir. 2006). Generally, a plaintiff's complaint need only satisfy the standard of Rule 8(a), which requires a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). "Rule 8(a)(2) still requires a 'showing,' rather than a blanket assertion, of entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 n. 3 (2007). That showing must consist of more than "a formulaic recitation of the elements of a cause of action" or "naked assertion[s] devoid of further factual enhancement." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citations omitted).

At this stage, all well-pleaded allegations in a complaint must be considered as true, *Albright v. Oliver*, 510 U.S. 266, 268 (1994), and all factual allegations must be construed in the light most favorable to the plaintiff. See *Harrison v.*

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pleading." Pursuant to Federal Rule of Civil Procedure 7(a), "pleadings" include a complaint, a counterclaim, a third-party complaint, an answer, and a reply, if ordered. Rule 12(f) may only address the papers listed in Rule 7(a). See, e.g., *Hrivnak v. NCO Portfolio Mgmt., Inc.*, 723 F.Supp.2d 1020, 1029 (N.D. Ohio 2010) ("While some courts have employed Fed.R.Civ.P. 12(f) to strike an affidavit or a brief, or portions thereof, there is no basis in the Federal Rules for doing so."). Because Defendants' reply memorandum is not a pleading, Plaintiffs' motion to strike will be denied.

*Westinghouse Savannah River Co.*, 176 F.3d 776, 783 (4<sup>th</sup> Cir. 1999) (citing *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4<sup>th</sup> Cir. 1993)). In evaluating the complaint, unsupported legal allegations need not be accepted. *Revene v. Charles Cnty. Comm'rs*, 882 F.2d 870, 873 (4<sup>th</sup> Cir. 1989). Moreover, legal conclusions couched as factual allegations are insufficient, *Iqbal*, 556 U.S. at 678, as are conclusory factual allegations devoid of any reference to actual events, *United Black Firefighters v. Hirst*, 604 F.2d 844, 847 (4<sup>th</sup> Cir. 1979).

Because Plaintiffs' amended complaint alleges fraud under §§ 10(b) and 20(a) of the Exchange Act, Plaintiffs must also satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9(b). See *Cozzarelli*, 549 F.3d at 629; *In re Medimmune, Inc. Sec. Litig.*, 873 F.Supp. 953, 960 (D.Md. 1995). Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Particularity of pleading is generally required with regard to the time, place, speaker and content of the allegedly false statement, as well as the manner in which the statements are false and the specific facts raising an inference of fraud. See *Medimmune*, 873 F.Supp. at 960; *In re Criimi Mae, Inc. Sec. Litig.*, 94 F.Supp.2d 652, 657 (D.Md. 2000).

The Private Securities Litigation Reform Act ("PSLRA") imposes additional pleading requirements on plaintiffs in securities fraud actions. As relevant here, the PSLRA requires the complaint to "specif[y] the statements alleged to have been misleading and the reasons why they were misleading" and to "support a reasonable belief that the statements were in fact misleading." *Teachers' Retirement System of LA v. Hunter*, 477 F.3d 162, 174-75 (4<sup>th</sup> Cir. 2007).

### **III. Analysis**

Plaintiffs allege in the amended complaint that Defendants knew, but failed to disclose at the time the first interim analysis results became available, that the PACT Trial was essentially destined to fail and, consequently, that TNFerade would never gain FDA approval. Despite this knowledge, they persisted in publicly expressing "optimism regarding the [first interim analysis] results as being predictive of PACT meeting its endpoint for overall survival, of a feasible path to commercialization of TNFerade, and of an expectation of GenVec securing a strategic partnership for TNFerade" (ECF No. 24, at 18), thereby artificially inflating the company's stock price.<sup>12</sup>

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<sup>12</sup> At no point did GenVec represent that it had an "expectation" of a partnership for TNFerade. Rather, it reported that it was seeking a partnership and, at various points, that it had engaged in discussions with potential partners.

In their papers opposing the motion to dismiss, Plaintiffs summarize the voluminous allegations of misleading statements contained in the amended complaint, with citations to the pleading, as follows:

Defendants' materially misleading statements to the investing public during the Class Period regarding the prospects for commercialization of TNFerade, purportedly supported by the data from the [first interim analysis] and PACT, and the Company's business, operations and prospects, included *inter alia*, that: there were "encouraging interim data from the trial" (March 12, 2009; [ECF No. 20 ¶ 61]); there were "encouraging top-line results of an interim analysis from . . . PACT" [*id.*]; "[e]ncouraging data in multiple indications continue to suggest TNFerade has the potential to become an important new therapeutic agent in the treatment of cancer" (March 13, 2009; [*id.* at ¶ 63]); Defendants planned to "commercialize [its] lead product candidate, TNFerade, for the treatment of . . . locally advanced pancreatic cancer" (March 16, 2009; [*id.* at ¶ 67]); "[o]ur commitment to TNFerade is based on encouraging clinical data . . . suggesting that TNFerade has the potential to become a significant new cancer drug" (May 8, 2009; [*id.* at ¶ 74]); "[t]he data we presented was encouraging and it gave us comfort moving forward with the program" [*id.*]; "we are encouraged by the survival trend being observed at this point in the trial" (June 1, 2009; [*id.* at ¶ 85]); "and we're hoping [the second interim analysis will] confirm the encouraging trend and the positive trend that we saw at the first look at the data" (August 7, 2009; [*id.* at ¶ 90]); "[a]nd we were encouraged last time, and we were disappointed, as you were, as a shareholder that the market reaction didn't reflect it" [*id.*]; "[w]e hope the data [in

the second interim analysis] will confirm the encouraging survival results seen in the first interim analysis and provide a clear path to approval of TNFerade for the treatment of locally advanced pancreatic cancer" [*id.*]; "[b]ased on the survival data obtained to date, we believe using TNFerade in the indication of locally advanced pancreatic cancer represents a feasible path to commercialization" (March 11, 2010; [*id.* at ¶ 129]); and "[e]merging clinical data suggest TNFerade may prolong the survival of patients with locally advanced pancreatic cancer when combined with front-line therapy" [*id.*].

(ECF No. 24, at 3-4 (internal emphasis removed)).

In Plaintiffs' view, these statements to investors - predominantly, through SEC filings, press releases, and conference calls - were "materially false and/or misleading when made because Defendants knew but did not disclose" that:

(i) the PACT Trial of TNFerade in patients with locally advanced pancreatic cancer was a failure because it did not increase survival in patients with locally advanced pancreatic cancer;

(ii) TNFerade was not clinically effective in patients with locally advanced pancreatic cancer;

(iii) there was no feasible path to commercialization for the use of TNFerade for locally advanced pancreatic cancer; and

(iv) the failure of the PACT Trial would have a material effect on the Company's financial condition because the Company did not have any near-term prospects of generating revenues from the commercial sale of their product candidates in their therapeutic or vaccine programs.

(ECF No. 20 ¶ 62(b)).<sup>13</sup>

The first count of the amended complaint asserts claims for violations of § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.<sup>14</sup> Section 10(b) prohibits "any person" from "us[ing] or employ[ing], in connection with the purchase or sale of any security registered on a national securities exchange[,] . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Its implementing regulation, SEC Rule 10b-5, provides:

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

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<sup>13</sup> As to each allegedly materially misleading statement, Plaintiffs assert that between two and four of these reasons apply.

<sup>14</sup> In count two, Plaintiffs allege violations by the individual defendants of § 20(a) of the Exchange Act, which imposes joint and several liability on a person who "controls any person liable under any provision of this chapter[.]" 15 U.S.C. § 78t(a). "[A] plaintiff must successfully allege a predicate violation of the Act in order to proceed under § 20(a)[.]" *Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 181 [n. 1] (4<sup>th</sup> Cir. 2009) (King J., concurring). Because the court will find that Plaintiffs have not successfully alleged a violation under § 10(b), their claim under § 20(a) must fail as well.

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,

in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5; see also *In re Constellation Energy Group, Inc. Sec. Litig.*, 738 F.Supp.2d 614, 633 (D.Md. 2010) ("Rule 10b-5 encompasses only conduct already prohibited by § 10(b)'") (quoting *In re Mut. Funds Inv. Litig.*, 566 F.3d 111, 119 (4<sup>th</sup> Cir. 2009)).

"Section 10(b) affords, by implication, a right of action to securities purchasers or sellers injured by its violations." *Matrix Capital*, 576 F.3d at 181. To state a plausible claim under § 10(b), the complaint must set forth facts showing:

(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation (that is, the economic loss must be proximately caused by the misrepresentation or omission).

*Id.* at 181 (internal marks and emphasis omitted) (quoting *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)).

Defendants contend that Plaintiffs' amended complaint is deficient as to the first, second, and sixth elements. Specifically, they challenge the sufficiency of the allegations that a material misrepresentation or omission was made, that the requisite strong inference of scienter arises, and that Plaintiffs' economic loss was proximately caused by any misrepresentation. Because the court agrees with Defendants as to the first point, it need not address the other two. See *Hunter*, 477 F.3d at 184 (agreeing with district court's conclusion that, "[b]ecause no misleading statement or omission was sufficiently alleged, the defendants could not have made misrepresentations or omissions intentionally or with sufficient recklessness"); *id.* at 173 n. 2 (defining "loss causation" as "a causal connection between the material misrepresentation and the loss" (citing *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42)).

To establish misrepresentation, the amended complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . state with particularity all facts

on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). The Fourth Circuit requires that the challenged statement or omission must be "factual," i.e., "one that is demonstrable as being true or false"; it "must be false, or the omission must render public statements misleading"; and "any statement or omission of fact must be material." *Longman v. Food Lion, Inc.*, 197 F.3d 675, 682 (4<sup>th</sup> Cir. 1999) (emphasis in original); see also *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1091-96 (1991) (under certain circumstances, opinions can be demonstrably true or false). As the court explained in *Longman*, 197 F.3d at 683:

These components - a *factual* statement or omission that is *false* or *misleading* and that is *material* - interact to provide a core requirement for a securities fraud claim. While opinion or puffery will often not be actionable, in particular contexts when it is both factual and material, it may be actionable. Thus, for example, a CEO's expression of "comfort" with a financial analyst's prediction of his company's future earnings was held not to be factual in that, as a future projection, it was not capable of being proved false. See *Malone v. Microdyne Corp.*, 26 F.3d 471, 479-80 (4<sup>th</sup> Cir. 1994); see also *Raab v. General Physics Corp.*, 4 F.3d 286, 289 (4<sup>th</sup> Cir. 1993) (holding similar statement predicting future growth not material because "the market price of a share is not inflated by vague statements predicting growth"). On the other hand, the Supreme Court has held that an opinion by board members to minority stockholders that the stock price of \$42 for the purchase of their shares was a "high value" and represented a "fair" transaction

could be both factual and material. See *Virginia Bankshares*, 501 U.S. at 1090-93, 111 S.Ct. 2749. In *Virginia Bankshares*, the Court noted that the opinions could be false and factual if the directors did not believe what they said they believed and proof could be had "through the orthodox evidentiary process." *Id.* at 1093, 111 S.Ct. 2749. In addition, the court found "no serious question" that the statements could be material in that shareholders, knowing that directors have greater knowledge and expertise as well as a fiduciary duty to shareholders, often act on what their board members say they believe. *Id.* at 1090, 111 S.Ct. 2749.

A statement or omission is material "if there is a substantial likelihood that a reasonable purchaser or seller of a security (1) would consider the fact important in deciding whether to buy or sell the security or (2) would have viewed the total mix of information made available to be significantly altered by disclosure of the fact.'" *In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 387 (4<sup>th</sup> Cir. 2005) (quoting *Longman*, 197 F.3d at 683). While Rule 10b-5 "prohibit[s] any misrepresentation of a fact deemed material," it "decidedly do[es] not prohibit any misrepresentation - no matter how willful, objectionable, or flatly false - of im[material] facts, even if it induces reactions from investors that, in hindsight or otherwise, might make the misrepresentations appear material." *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 656 (4<sup>th</sup> Cir. 2004) (emphasis in original). Ultimately, "[t]he

inquiry is whether, read as a whole, the [statements or omissions] "would have misled a reasonable investor about the nature of the securities." *In re Constellation Energy*, 738 F.Supp.2d at 624-25 (citing *Recupito v. Prudential Securities, Inc.*, 112 F.Supp.2d 449, 455 (D.Md. 2000)).

The instant case is, as Defendants assert, essentially an "omissions case." (ECF No. 21-1, at 20). Plaintiffs do not challenge the truth of any aspect of the first interim analysis data released to the public; indeed, they acknowledge that "the affirmative misrepresentations alleged in the [c]omplaint [do not arise] from the accuracy of the data, a poorly designed trial[,] or inaccurate financial results[.]" (ECF No. 24, at 18). They further acknowledge that investors were armed with all facts necessary to interpret the first interim analysis results and that the market knew they were a mixed bag. As one analyst observed, the data "look[ed] positive" on the surface and there was "reason for optimism" insofar as the results showed that "[p]atients with pancreatic cancer treated with TNFerade plus standard of care demonstrated a 25% lower risk of death than similar patients with standard of care alone[.]" (ECF No. 21-34, at 2). Moreover, "the interim hazard ratio for TNFerade of 0.75 [compared] favorably with similar hazard ratios observed in studies of other approved and successful cancer drugs[.]" (*Id.* at 3). Questions remained, however, as to

whether the drug would "produce a hazard ratio in the ballpark of 0.75 at the final analysis of the study," and there were indications that it would not because the ratio was "likely to increase as [the] study mature[d], with more patients enrolled and more patients dying." (*Id.* at 2-3). Notably, upon release of the first interim analysis results, "GenVec shares sank[.]" (*Id.* at 2).

The critical question as to the first element, then, is whether Defendants' omission of the alleged fact that they privately held the opinion that the PACT Trial would ultimately fail rendered their public statements of optimism misleading. In arguing that it did not, Defendants cite *Padnes v. Scios Nova Inc.*, No. C 95-1693 MHP, 1996 WL 539711 (N.D.Cal. 1996). In *Padnes*, like the instant case, representatives of a biopharmaceutical company "expressed positive opinions and enthusiasm about the future" of a drug based on an interim clinical study, which did not later come to fruition. *Id.* at \*6. The court determined, in relevant part, that "plaintiffs have not pled facts sufficient to show there was no reasonable basis for relying on the findings of the [] study or that there were undisclosed facts tending to seriously undermine the accuracy of defendants' opinions." *Id.* In so holding, it explained that "defendants' opinions about the study's findings were not the only reasonable ones," citing a negative market

analysis, and that "neither facts showing reasonable people could have disagreed with defendants' beliefs nor the mere fact that the Phase III tests were unsuccessful . . . amount to allegations that there was no reasonable basis for the opinions which were expressed." *Id.*

According to Defendants, Plaintiffs similarly "have alleged no facts that support the assertion that Defendants had concluded based on the [f]irst [i]nterim [a]nalysis that TNFerade was doomed to failure." (ECF No. 21-1, at 28). Plaintiffs argue in rebuttal that, "[i]n contrast to *Padnes*, where '[r]easonable minds could differ with respect to the value of the [] study in determining the therapeutic effects of [the drug],' here, there was no disagreement of opinion, reasonable or otherwise, over how to interpret the [first interim analysis results]." (ECF No. 24, at 22). They contend that "[t]hese statistically insignificant data were in no way predictive that PACT would meet its efficacy endpoint or that there was a feasible path to commercialization for TNFerade." (*Id.*).

Plaintiffs' argument finds no support in the record, which reflects that the market was fully aware of the potentially negative implications of the first interim analysis, as was the DSMB, which independently recommended that the trial be continued, and the FDA, which granted fast track approval and orphan drug designation based on the same results. While the

statements of Plaintiffs' CWs support that the first interim analysis results may not have been what Defendants had hoped for, there was certainly a reasonable basis for believing that TNFerade plus standard of care treatment might be found to prolong the lifespan of pancreatic cancer patients, as compared to those receiving standard of care alone. "[T]he Supreme Court has repeatedly cautioned that allegedly fraudulent corporate statements must be examined in context and in light of the 'total mix' of information made available to investors." *Phillips v. LCI Intern., Inc.*, 190 F.3d 609, 615 (4<sup>th</sup> Cir. 1999) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988); *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). Here, the PACT Trial tested TNFerade for the treatment of patients with pancreatic cancer, a particularly fatal form of the disease for which existing treatments were largely ineffective; thus, any potential benefit to patients in terms of extending lifespan represented cause for hope. While the first interim analysis data may have suggested that the benefits of TNFerade would dissipate over time, it also showed that patients receiving the drug experienced a 25% lower death rate at the first interval.

Under Plaintiffs' theory, Defendants were essentially negligent, if not outright fraudulent, in continuing the trial past the first interim analysis, as nothing more was known to

them until the second interim analysis results were available.<sup>15</sup> But they do not allege any wrongdoing by Defendants in proceeding with the second interim analysis, and the putative class period does not begin until approximately four months after the first interim results were released. By that time, Defendants had already publicly expressed that the results were "encouraging" and that they "justif[ied] moving forward with the trial." (ECF No. 21-22, at 5). It is unclear how the expression of similar opinions during the class period induced Plaintiffs to purchase GenVec shares. Indeed, it seems far more likely that the market reacted favorably to objective indications that the trial might be successful, such as the FDA's fast track and orphan drug designations.

In *Virginia Bankshares*, 501 U.S. at 1095-96, the Supreme Court held that a statement of belief can be actionable only "as a misstatement of psychological fact of the speaker's belief in what he says" where there is "objective evidence" of the falsity of that belief. Here, the objective evidence was publicly available and susceptible to differing interpretations by

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<sup>15</sup> At one point in their opposition papers, Plaintiffs suggest that optimistic statements made by Defendants after the second interim analysis data became available were misleading because, by that point, Defendants' fear that the PACT Trial would fail had been realized. (See ECF No. 24, at 11 n. 9). Because this argument finds no support in the amended complaint - which relates entirely to misrepresentations based on the first interim analysis data - the court will not consider it here.

reasonable minds. There was, quite simply, a reasonable basis for Defendants' expressions of optimism, and the fact that the PACT Trial was ultimately unsuccessful was a known risk to investors. See *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 48 (1<sup>st</sup> Cir. 2008) ("the investing public is well aware that drug trials are exactly that: trials to determine the safety and efficacy of experimental drugs. And so trading in the shares of companies whose financial fortunes may turn on the outcome of such experimental drug trials inherently carries more risk than some other investments. This is true even when the FDA has given fast-track approval to a new drug."); *In re Pfizer, Inc. Sec. Litig.*, 538 F.Supp.2d 621, 631 (S.D.N.Y. 2008) ("'[C]orporate officials need not present an overly gloomy or cautious picture' so long as 'public statements are consistent with reasonably available data'" (quoting *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000))); *In re Sierra Wireless, Inc. Sec. Litig.*, 482 F.Supp.2d 365, 367 (S.D.N.Y. 2007) ("securities laws neither require corporate officers to adopt a crabbed defeatist view of the company's business prospects nor permit dissatisfied shareholders to assert serious allegations of fraud based on the perfect hindsight afforded by the passage of time"). Particularly when considered under the the heightened pleading standards of Rule 9(b) and the PSLRA, the allegations in the amended complaint are insufficient to

show that Defendants' public statements were false at the time they were made.

Even if falsity had been shown, Plaintiffs have not demonstrated that the challenged statements were material. Generally, "[s]oft expressions of optimism which are analogous to puffing' have been held not to constitute actionable misrepresentations" because they "are simply not material." *In re Constellation Energy*, 738 F.Supp.2d at 625 (quoting *In re USEC Sec. Litig.*, 190 F.Supp.2d 808, 822 (D.Md. 2002)); see also *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004) ("expressions of puffery and corporate optimism do not give rise to securities violations"); *Glen Holly Entertainment, Inc. v. Tektronix, Inc.*, 352 F.3d 367, 379 (9<sup>th</sup> Cir. 2003) (optimistic statements regarding product quality and marketing efforts "were generalized, vague and unspecific assertions, constituting mere 'puffery' upon which a reasonable consumer could not rely"); *Phillips*, 190 F.3d at 615 ("hyperbole and speculation cannot give rise to a claim of securities fraud"); *Raab*, 4 F.3d at 289 ("'Soft,' 'puffing' statements . . . generally lack materiality because the market price of a share is not inflated by vague statements predicting growth").

In their opposition papers, Plaintiffs properly characterize their challenge as Defendants placing "an unjustifiably positive spin on the data available at the time of

the [first interim analysis] by using terms like 'encouraging' and 'bullish[.]'" (ECF No. 24, at 5). Such "vague and general statements of optimism constitute no more than 'puffery' and are understood by reasonable investors as such." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3<sup>rd</sup> Cir. 1999) (internal marks and citation omitted). Accordingly, they are immaterial and not actionable under § 10(b). *See Greenhouse*, 392 F.3d at 656.<sup>16</sup>

Plaintiffs have requested leave to amend their complaint in the event that Defendants' motion to dismiss were to be granted. Pursuant to Federal Rule of Civil Procedure 15(a)(2), courts should grant leave to amend a pleading "freely . . . when justice so requires." Leave should be denied, however, where "the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the

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<sup>16</sup> Plaintiffs further contend that Defendants violated Item 303 of SEC Regulation S-K, which requires a registrant to "[d]escribe any known trends or uncertainties that have had or that the registrant expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. § 229.303(a)(3)(ii). "[T]here is no private right of action under SEC Regulation S-K," however, and "because the materiality standards under [Rule] 10b-5 and Regulation S-K 303 differ significantly, a violation of Regulation S-K does not lead to a failure to disclose under 10b-5." *Iron Workers Local 16 Pension Fund v. Hilb Rogal & Hobbs Co.*, 432 F.Supp.2d 571, 583 (E.D.Va. 2006). Where "plaintiffs have failed to plead any actionable misrepresentation or omission under [Rule 10b-5], SK-303 cannot provide a basis for liability." *Oran v. Stafford*, 226 F.3d 275, 288 (3<sup>d</sup> Cir. 2000).

amendment would be futile." *HCMF Corp. v. Allen*, 238 F.3d 273, 276 (4<sup>th</sup> Cir. 2001) (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 242 (4<sup>th</sup> Cir. 1999) (internal marks omitted)). "An amendment is futile when the proposed amendment is clearly insufficient or frivolous on its face, or if the amended claim would still fail to survive a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6)." *El-Amin v. Blom*, Civ. No. CCB-11-3424, 2012 WL 2604213, at \*11 (D.Md. July 5, 2012) (internal marks and citations omitted).

Plaintiffs have not suggested how a second amended complaint would address the infirmities of the first amended pleading, nor does it appear that they could. There is certainly no shortage of facts alleged in the amended complaint, which spans over 150 pages, but those facts simply do not support that Defendants' alleged misrepresentations or omissions are actionable under the Exchange Act. Thus, "in light of the fundamental deficiencies in [P]laintiffs' theory of liability," further amendment would be futile. *Cozzarelli*, 549 F.3d at 630. Accordingly, the amended complaint will be dismissed with prejudice.

**IV. Conclusion**

For the foregoing reasons, Defendants' motion to dismiss will be granted. A separate opinion will follow.

\_\_\_\_\_/s/\_\_\_\_\_  
DEBORAH K. CHASANOW  
United States District Judge