IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

In Re Human Genome Sciences Inc. Securities Litigation	*	Civil Action No.: RWT 11cv3231
THIS DOCUMENT RELATES TO ALL ACTIONS	*	CLASS ACTION

MEMORANDUM OPINION

Benlysta® is a drug developed and marketed by Defendants Human Genome Sciences, Inc. ("HGS") and Glaxo Smith Kline, PLC ("GSK") for the treatment of lupus. It was approved by the FDA in 2011, and was the first new treatment for lupus approved in 56 years. During several clinical trials involving more than 1,900 patients, Defendants learned that three participants had committed suicide. Defendants allegedly concealed these facts from investors, who consequently suffered significant stock losses when the information later became public. These investors, the Plaintiffs in the present case, have brought this class action charging violations of the anti-fraud provisions of the federal securities laws.

Claims of security fraud carry a heightened pleading standard. A plaintiff must establish not only that the defendant acted wrongfully, but that it acted with scienter (*i.e.*, wrongful intent or purpose) as opposed to mere negligence. As Plaintiffs have failed to allege facts that give rise to a strong inference that Defendant purposefully concealed the adverse effects of Benlysta, Defendants' Motions to Dismiss [ECF Nos. 29 and 30] must be granted.

Background[1]

HGS is a biopharmaceutical company that developed a breakthrough lupus drug called Benlysta. *See* Am. Compl. ¶ 25, ECF No. 25. Beginning in October 2003, HGS started its Phase 2 "blinded" drug study, known as L02. *Id.* ¶ 28; *see* HGS Mot. Dismiss Ex. E, Journal of the American College of Rheumatology, ECF No. 29-7. During this clinical trial, one patient committed suicide.[2] *See* Am. Compl. ¶ 72.

The L02 study ended in February 2006 and HGS began a second study, LBSL99, which followed former L02 patient participants for a number of years. *Id.* ¶ 28. Unlike the Phase 2 L02 blind study, the LBSL99 extension study was "unblinded" and had no control group. *Id.* During the course of the LBSL99 study, one patient committed suicide and two more attempted suicide. *Id.*

Before HGS began its Phase 3 studies of Benlysta, it entered into a co-development and co-commercialization agreement with GSK. *Id.* ¶ 29. Under the terms of the agreement, GSK would assist with the Phase 3 trials. *Id.* The Phase 3 trials consisted of the BLISS-76 study and the BLISS-52 study. *Id.* ¶ 33. One suicide occurred in the BLISS-52 study; no suicides occurred in the BLISS-76 study. *Id.* ¶ 72.

Throughout the course of Benlysta's development and prior to Benlysta's ultimate approval by the FDA, HGS and GSK issued various press releases touting Benlysta's safety and

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[1] These facts are drawn from Plaintiffs' amended complaint and are assumed to be correct for purposes of evaluating the motions to dismiss. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 544 (2007). In a securities fraud action, the Court may also consider statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the Securities and Exchange Commission, analyst reports, documents upon which Plaintiffs relied in bringing suit, and matters of which the Court may take judicial notice. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

[2] Patients with lupus are generally known to have a higher suicide rate than the general population. *See* Am. Compl. ¶ 88.

efficacy. *Id.* ¶¶ 35-65. HGS's officers also conducted analyst calls and made investor presentations in which they discussed the Phase 2 L02 trial, the Phase 3 BLISS-52 and BLISS-76 trials, and Benlysta's safety profile. *Id.* On several occasions, HGS discussed the correlation between suicide and Benlysta, but only with respect to the suicides in the Phase 2 L02 and the Phase 3 BLISS-52 studies. *Id.* The attempted and actual suicides in the LBSL99 extension study were not mentioned. *Id.*

In November of 2006, HGS issued a press release informing the investing public that the results of the Phase 2 blinded L02 trial would be discussed at the American College of Rheumatology's annual conference. *See* HGS Mot. Dismiss Ex. C, November 14, 2006 Press Release, ECF No. 29-5 at 1. At the conference, HGS's officers revealed that an individual committed suicide during the Phase 2 blinded L02 trial, but that the investigator had determined that the suicide was "not related" to Benlysta. *See* HGS Mot. Dismiss Ex. D, Power Point, ECF No. 29-6 at 11.

In September of 2009, physicians and an HGS executive published the results of the Phase 2 blinded L02 trial in the Journal of the American College of Rheumatology, discussing the single suicide associated with that particular study. *See* HGS Mot. Dismiss Ex. E, Journal of the American College of Rheumatology, ECF No. 29-7 at 8.

In November of 2009, HGS held a conference call for all investors. *See* HGS Mot. Dismiss Ex. G, November 2, 2009 Press Release, ECF No. 29-9; Amend. Compl. ¶ 48. During the conference call, a Citigroup analyst discussed the suicide in the Phase 2 blinded L02 trial and raised questions about the suicide in the Phase 3 blinded BLISS-52 trial. *See* HGS Mot. Dismiss Ex. F, November 2, 2009 Transcript Analyst Call, ECF No. 29-8 at 8. After the call, Citigroup

published an analyst note in which it discussed the two suicides. *See* HGS Mot. Dismiss Ex. H, November 2, 2009 Citigroup Analyst Report, ECF No. 29-10 at 8.

HGS executives did make vague, passing references to the ongoing unblinded LBSL99 study on three occasions. First, on September 9, 2009, HGS Chief Commercial Officer Labinger made the following statement at the Thomas Weisel Partners Healthcare Conference:

> So first turning to BENLYSTA, again potentially the first new lupus drug in 50 years. This is the primary endpoint that we saw in BLISS-52, the first of our two Phase 3 global trials. The safety was very impressive. No difference in overall adverse events or serious adverse events or infections, which were a category of interest for us. No difference in fatalities across those groups for BENLYSTA and placebo. You see a list of the common adverse events, but there are no differences between groups and those either. There were no malignancies reported in the trial overall. So we're very pleased so far with the safety profile. We've got patients from our Phase-II program on drugs through four to five years now and see a similar experience and we are obviously diligently track [sic] safety going into the future as we get larger numbers on treatments for longer periods of time.

See Am. Compl. ¶ 43.

Second, on June 15, 2010, HGS CEO Watkins made the following presentation to investors at the Goldman Sachs Global Healthcare Conference:

> There was no data we saw in there which did not confirm for us a continued strong therapeutic benefit. I think of equal importance here is the issue of safety. We now have, from the Phase 2 study, and we've continued many of those patients, some patients from our Phase 2 study, which was unblinded in '05, have continued on study drug. Now, some have been on study drug now for as much as five, six years, I think we have a few on six years . . . . We will continue – we show that data every six months at EULAR or ACR. So, maybe this week, you will see that data.
>
> What we see from those patients, as well as from the patients in both of the Phase 3 studies is a very positive safety profile. And as you know, one of the areas of concern to physicians, when they prescribe long-term immunomodulatory agents, is what is the impact on the patient's overall well-being over a considerable period of time. Now we will continue, we

> must continue to be very diligent in tracking safety on a continual basis, we understand that. But certainly what we will present –what we have presented to the FDA and the EUA we believe is a very positive profile relative to both efficacy and safety.

Id. ¶ 65.

Third, on September 13, 2010, HGS CEO Watkins made the following statement at Morgan Stanley Global Healthcare Unplugged Conference:

> So I think they're going to be very pleased with the body of data that they see, both in terms of effect and equally important in terms of safety. Recall that our Phase II study that we did, which had landed in 2005 was a 449-patient study. Nearly 200 or 50% of those patients, 250 of those patients, are still on long-term rollover trial. These were – a voluntary extension trial which the patients could move onto. So we have a safety database that extends, in the case of some patients, back – some patients have been on therapy for approaching seven years now. Obviously, we want a much bigger patient database as we move out of registration into marketing. But certainly for a drug that's still experimental, if you will, to have some patients have been on drug for that long a time offers us and regulators an excellent window into how the drug will perform on a long-term basis. And we're very confident that this drug does well on a safety basis. I think that's going to be a very important feature of commercialization.

Id. ¶ 70

Although HGS officers discussed general aspects of the LBSL99 study, the details of the actual study—*i.e.*, a suicide and two attempted suicides—were never publically disclosed until November 12, 2010. Am. Compl. ¶ 78. In its Biologics License Application (BLA) for Benlysta, HGS included information regarding the single suicide and the two attempted suicides in the unblinded LBSL99 trial.[3] On November 12, 2010, the FDA publically posted its analysis

[3] The information included in the BLA regarding the LBSL99 study is as follows:

> Study LBSL99 (open-label extension of LBSL02): Subject US023-005 was a 65 year-old white female with SLE. She received her 1st dose of 10.0 mg/kg belimumab on 15Mar04 and completed both the 52-week treatment phase and the 24-week extension phase at that dosage. She

of Benlysta based on HGS' BLA in advance of a FDA committee meeting, and referenced the third known suicide and the two attempted suicides in the ongoing unblinded LBSL99 extension trial. *Id.* One day after that disclosure, HGS's stock dropped 10 percent. *Id.* ¶ 82.

Several days later, on November 15, 2010, FierceBiotech published an article discussing the Benlysta BLA application that had been disclosed by the FDA. *Id.* ¶ 86. The article quoted

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> continued to receive 10.0 mg/kg belimumab in LBSL99 (starting on 27Sep05). The subject's last dose of belimumab was on 21Mar06 . . . . In the morning of 15Apr06, the subject was found dead in bed. It initially appeared that she had taken all of her remaining anti-hypertensive medications. The site confirmed that the subject had no history of depression and no ongoing AEs. The subject was scheduled to receive her next dose of belimumab on 17Apr06. An autopsy report revealed that the subject was found with superficial cuts to the wrists and empty pill bottles. Her death was ascribed to oxycodone and alcohol intoxication.
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> Study LBSL99: Subject US006-0008 is a 44-year-old female with systemic lupus erythematosus (SLE) who participated in Study LBSL99. The subject received her first dose of belimumab (1 mg/kg) on 27Jul04 in LBSL02, her first dose of belimumab (10 mg/kg) in the extension phase on 30Aug05, and her first dose of belimumab in LBSL99 on 07Feb06. Medical history is significant for depression, hypertension, obesity, and smoking. No previous psychiatric outpatient or inpatient hospitalizations . . . . On 26Dec08, 21 days after her most recent dose of belimumab, the subject's husband found her sleepy and unresponsive and called the paramedics. She was transported via ambulance to the local hospital . . . . She reportedly took a drug overdose while intoxicated and was subsequently admitted for suicide gesture . . . . The subject reported being lonely, discouraged, and upset with her sister. In addition, she reported stress secondary to family problems. She did not seek out help, but started drinking alcohol (unknown type) and took some pills (not identified and amount not provided by subject). She reported her plan was to hurt herself, although she was vague about a suicidal attempt. She reported not being suicidal, just reaching out for help. She had no delusions and repeatedly denied plans to kill herself. She was not considered psychotic.
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> Subject US003-0013 in ongoing long-term extension study LBSL99, receiving 10 mg/kgbelimumab, reported depression and suicide attempt. No further details were provided.
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> *See* Am. Compl. ¶ 78.

certain analysts as stating that "suicidality risk likely was what had investors spooked Friday . . . [but] we consider it unlikely that a targeted biologic is increasing suicidality in a patient population already known to be at increased risk." *Id.* The article also quoted analyst Joseph Schwartz as stating that, "We saw no new data that [HGS] has not previously released that looked less positive than what has previously been presented, and continue to expect a positive panel vote." *See* HGS Mot. Dismiss Ex. P, November 15, 2010 FierceBiotech Article, ECF No. 29-18.

On March 9, 2011, the FDA approved Benlysta for the treatment of lupus. *See* HGS Mot. Dismiss Ex. L, FDA Press Release, ECF No. 29-14.

On November 10, 2011, Plaintiff Roger Miraglia filed a class action complaint in this Court against HGS, some of that company's senior officers and directors, and GSK. *See* ECF No. 1. On November 21, 2011, Davin Pokoik filed a nearly identical complaint in this Court. *See* No. 11-3353, ECF No. 1. On January 20, 2012, the Court issued a show cause order as to why both the Miraglia and Pokoik actions should not be consolidated. *See* ECF No. 13. On February 17, 2012, both Plaintiffs filed a stipulation agreeing to consolidate the cases and appointing a lead Plaintiff and lead Counsel. *See* ECF No. 17.

On March 20, 2012, this Court appointed Davin Pokoik as lead Plaintiff and established a briefing schedule. *See* ECF No. 24. On April 27, 2012, the lead Plaintiff filed an amended class action complaint against HGS and GSK as well as HGS CEO Thomas Watkins, HGS Chief Commercial Officer Barry Labinger, HGS CFO David Southwell and HGS VP of R&D David Stump. *See* Am. Compl., ECF No. 25. The action was brought on behalf of those purchasing the common stock of HGS between July 20, 2009 and November 11, 2010, inclusive (the "Class Period") for violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934. *Id.*

Specifically, the complaint alleges that Defendants failed to disclose that Benlysta was associated with suicide in clinical drug trials conducted by the Company, while selling over $800 million worth of shares to investors at artificially inflated prices during the Class Period. The complaint alleges that when the FDA posted its analysis of Benlysta on the Internet on November 12, 2010, investors learned for the first time of the association between Benlysta and suicide in clinical trials of the drug, causing HGS's common stock price to decline precipitously.

On May 25, 2012, Defendants HGS and GSK filed their respective motions to dismiss. *See* ECF Nos. 29 and 30. After the motions were fully briefed, a hearing on the motions was held on September 5, 2012.

Standard of Review

A motion to dismiss under Rule 12(b)(6) tests the sufficiency of a complaint; importantly, it does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992). "Federal Rule of Civil Procedure 8(a)(2) requires only a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) (internal quotation marks omitted). The complaint need not assert "detailed factual allegations," but must contain "more than labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Id*. "Factual allegations must be enough to raise a right to relief above the speculative level." *Id*. The Court "must assume that the allegations of the complaint are true and construe them in the light most favorable to the plaintiff." *Martin*, 980 F.2d at 952. In the final analysis, a motion to dismiss for failure to state a claim should not be granted unless it appears to a certainty that the plaintiff would be entitled to no relief under any set of facts which could be

provided in support of the claims. *See McNair v. Lend Lease Trucks, Inc.*, 95 F.3d 325, 328 (4th Cir. 1996).

In the securities context, a motion to dismiss is also subject to the heightened pleading standards contained in the Private Securities Litigation Reform Act ("PLSRA"), which requires plaintiffs to state with particularity both the facts constituting the alleged violation, and facts evidencing scienter, *i.e.*, the defendant's intention "to deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194, n. 12 (1976); *see* 15 U.S.C. § 78u–4(b)(1). Specifically, a securities fraud claim will only survive a 12(b)(6) motion if the complaint creates a "strong inference of scienter." In the seminal case of *Tellabs, Inc. v. Makor Issues & Rights, Ltd*, the Supreme Court provided:

> [C]ourts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice. *See* 5B Wright & Miller § 1357 (3d ed. 2004 and Supp. 2007). The inquiry, as several Courts of Appeals have recognized, is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard. *See, e.g., Abrams v. Baker Hughes Inc*., 292 F.3d 424, 431 (5th Cir. 2002); *Gompper v. VISX, Inc*., 298 F.3d 893, 897 (9th Cir. 2002). *See also* Brief for United States as Amicus Curiae 25.

551 U.S. 308, 310 (2007).

The Fourth Circuit has taken this language to mean that a court may look beyond a plaintiff's discrete allegations to additional facts, especially 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 [the plaintiff's] complaint." *Cozzarelli v. Inspire Pharms., Inc*., 549 F.3d 618, 625 (4th 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." *Johnson v. Pozen Inc*., No. 7-599, 2009 WL 426235, at *2 (M.D.N.C. Feb. 19, 2009) (citing *In re Inspire Pharms., Inc. Sec. Litig*., 515 F. Supp. 2d 631, 637 (M.D.N.C. 2007)). Accordingly, the Court may consider certain exhibits attached to the motions to dismiss, in addition to the Plaintiffs' complaint.

Discussion

I. Liability Standards under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

Plaintiffs have brought claims against the Defendants under sections 10(b) and 20(a) of the Securities Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and the regulation promulgated thereunder, Rule 10b–5, 17 C.F .R. § 240.10b–5.

Section 10(b) creates a private right of action for purchasers or sellers of securities who have been injured by the statute's violation. *See, e.g., Superintendent of Ins. of State of N.Y. v. Bankers Life & Cas. Co*., 404 U.S. 6, 13 n. 9 (1971).[4] Under Section 10(b), it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or

[4] Pursuant to section 10(b), the SEC has promulgated Rule 10b–5, which makes it unlawful:

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

See 17 C.F.R. § 240.10b–5.

deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe . . ." 15 U.S.C. § 78j(b).

To establish securities fraud liability under Section 10(b) of the Exchange Act and Rule 10b–5, a plaintiff must allege and ultimately prove the following:

1. The defendant made a material misrepresentation or omission;

2. The defendant acted with scienter;

3. The material misrepresentation or omission was made in connection with the purchase or sale of a security;

4. The plaintiff relied upon the material misrepresentation or omission;

5. The plaintiff suffered an economic loss as a result of his investment; and

6. The plaintiff's economic loss was proximately caused by the alleged misstatement.

See Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1317-1318 (2011).

A fact 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." *See In re PEC Solutions, Inc. Sec. Litig*., 418 F.3d 379, 387 (4th Cir. 2005). Scienter may be proven by either intentional misconduct or recklessness, but not mere negligence. *Id.*

Section 20(a) of the Exchange Act creates a mechanism for joint and several liability. In this regard, Section 20(a) provides:

> [E]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling

> person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

See 15 U.S.C. § 78t(a). Here, Plaintiffs seek to impose joint and several liability against CEO Thomas Watkins, Chief Commercial Officer Barry Labinger, CFO David Southwell and VP of R&D David Stump, all officers of HGS, as "controlling persons" under section 20(a).

II. Defendants Lack the Scienter Necessary for Liability.

Defendants assert that the complaint should be dismissed because Plaintiffs have failed to plead facts capable of supporting an inference of scienter. In response, Plaintiffs argue that Defendants behaved dishonestly by concealing the suicide results from investors and violated their duty to disclose such information. As explained below, this Court concludes that scienter has not been alleged sufficiently in this case because the facts before it more plausibly suggest that HGS acted innocently or, at most, negligently, in not disclosing the additional suicide information from the LBSL99 study, rather than that HGS acted with deliberate intent to mislead investors.

A. The scienter standard.

A Section 10(b) claimant must establish that a defendant acted with scienter. The Supreme Court has defined "scienter" as "a mental state embracing intent to deceive, manipulate, or defraud." *See Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 n.2 (1976). Under Fourth Circuit law, negligence is not enough to prove scienter; a plaintiff must show either intentional misconduct or such severe recklessness that the danger of misleading investors was "either known to the defendant or so obvious that the defendant must have been aware of it. *See Cozzarelli v. Inspire Pharmaceuticals Inc.*, 549 F.3d 618, 623 (4th Cir. 2008) (citing *Ottmann v. Hanger Orthopedic Group, Inc*., 353 F.3d 338, 343–44 (4th Cir. 2003)). As the Supreme Court explained in *Tellabs*, scienter in the securities litigation context exists only where the plaintiff

makes specific allegations of false statements that give rise to strong inference that the defendant acted with scienter. 551 U.S. at 310. The Fourth Circuit has distilled the strong inference standard to the following test: "[W]hen the facts as a whole more plausibly suggest that the defendant acted innocently—or even negligently—rather than with intent or severe recklessness, the action must be dismissed" for lack of scienter. *Cozzarelli*, 549 F.3d at 624.

In securities litigation cases premised upon a drug company's partial non-disclosure of drug trials to the investing public, the key inquiry is whether the non-disclosure at issue results in a suspiciously incomplete data set that yields a strong inference of scienter. *See, e.g., In re Forest Laboratories Sec. Litig.*, No. 05-2827, 2006 WL 5616712 (S.D.N.Y. July 21, 2006) (finding scienter where company actively advised physicians to use drug "off label" but failed to disclose studies showing increased risk of suicide associated with off label use). In *Alaska Electrical Pension Fund*, a case relied on by Plaintiffs, the court found scienter even though the defendant drug company eventually disclosed adverse test results to the FDA. 554 F.3d 342 (3d Cir. 2009). The defendant in that case misled The Journal of the American Medical Association, as well as the investment community, by submitting incomplete data with respect to a particular trial and using it as a basis for publishing information about that trial in the national journal. *Id.* Similarly, in *City of Livonia Employees' Retirement System*, No. 07-10329, 2010 WL 3910265 (S.D.N.Y. Sept. 29, 2010), another case relied on by the Plaintiffs, the court found scienter even though the defendant drug company submitted the complete results of a specific Phase 3 drug trial known as Study 315 to the FDA, because the defendant simultaneously disclosed only favorable portions of that drug trial to the public.

B. HGS' decision to withhold the results from the ongoing, unblinded LBSL99 does not create an inference of scienter.

There are insufficient allegations of scienter in this case because HGS's disclosure of the complete results of the blinded Phase 2 and Phase 3 studies, but not the ongoing, unblinded LBSL99 study, did not result in the presentation of a misleading data set to the public. First, unlike the defendants in *Alaska Electrical Pension Fund* or *City of Livonia Employees' Retirement System*, HGS did not selectively disclose the favorable aspects of its drug trials while completely omitting the unfavorable aspects. Rather, in discussing the Phase 2 L02 and Phase 3 BLISS-52 test results, HGS disclosed that one suicide occurred during each study. Although HGS did characterize the suicide in the Phase 2 L02 study as "unrelated" to Benlysta, this characterization was actually a conclusion of the study itself, not the company's independent interpretation. *See* HGS Mot. Dismiss Ex. E, Journal of the American College of Rheumatology, ECF No. 29-7 at 8 ("Two deaths (1 suicide…) were reported, and neither was considered to be related to the study drug by the investigator.").

Second, HGS did not give the public misleading information regarding the results of the unblinded LBSL99 study. *Cf. City of Livonia Employees' Retirement System,* 2010 WL 3910265 at * 2 (finding scienter because drug company executives stated that Study 315 showed that the new drug was similar to a previously approved drug in terms of efficacy, safety, and tolerability and had no new side effects, when in fact the drug was associated with serious side effects in the study). HGS CEO Watkins and HGS Chief Commercial Officer Labinger only made three passing references to a nameless study that is possibly the LBSL99 study. In the first reference, HGS CEO Watkins did not discuss specific LBSL99 outcomes except to call them "similar" to the Phase 2 L02 and Phase 3 BLISS-52 outcomes, studies which also had one instance of suicide. *See* Am. Compl. ¶ 43 ("We've got patients from our Phase-II program on drugs through four to

five years now and see a similar experience [to BLISS-52] and we are obviously diligently track [sic] safety going into the future as we get larger numbers on treatments for longer periods of time."). In the second reference, HGS CEO Watkins merely informed the public about an ongoing Phase 2 study that had produced "a very positive safety profile." *Id.* ¶ 65. In the third reference to the LBSL99 study, HGS Chief Commercial Officer Labinger informed investors that an examination of HGS's database of long-term Benlysta patients suggested that the drug is safe and well-tolerated over time. *Id.* ¶ 70.

Because the above statements are all factually accurate, albeit with a positive spin, scienter would have to be inferred from the company's omission of more specific details about the study, including the suicides. While it is possible to infer that HGS executives deliberately omitted facts about the attempted and actual suicides in order to hoodwink investors, it is just as plausible, indeed more so, to infer that they only offered vague details about the study because it was ongoing. *Cf. Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309 (2011) (where defendant drug company did not disclose reports indicating adverse effects of drug, scienter could be inferred from defendant's presentation of false information to investors regarding the drug's side effects). As Defendants had already disclosed the suicides during the other studies, it seems implausible, without additional factual support, to infer that they masterminded a cover-up of that same information from a third study.

Finally, Defendants had no duty to disclose any information about unblinded study LBSL99, such that their failure to do so yields an inference of deliberate wrongdoing. Section 10(b) "do[es] not create an affirmative duty to disclose any and all material information." *Matrixx*, 131 S.Ct. at 1321. Instead, it imposes only a duty to avoid certain omissions when an incomplete statement might mislead the public. *See City of Ann Arbor Employees' Retirement*

System v. Sonoco Products Co., 827 F. Supp. 2d 559, 580 (D.S.C. 2011) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n. 17 (1988)) ("Silence, absent a duty to disclose, is not misleading under Rule 10b–5," even with respect to material information). Defendants never even mentioned the unblinded LBSL99 study by name, or gave any concrete details about its results. Thus, the non-disclosure of the suicides during that study is hardly a misleading omission arising from an incomplete presentation of information about the study.

In sum, there are simply insufficient allegations of intentional or reckless omissions or falsities by the Defendants such that scienter, a necessary element of Plaintiffs' claims under Section 10(b), may be inferred. Moreover, because Plaintiffs' Section 10(b) claims fail as to HGS, Plaintiffs' Section 20(a) claims also must fail against HGS' officers.

Conclusion

For the foregoing reasons, Defendants' Motions to Dismiss [ECF Nos. 29 and 30] shall be GRANTED. A separate Order follows.

Date: March 26, 2013

/s/
ROGER W. TITUS
UNITED STATES DISTRICT JUDGE