UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE NEOPHARM, INC.	**)**	**02 C 2976**
SECURITIES LITIGATION	**)**	**Judge Joan H. Lefkow**
	)	

OPINION AND ORDER

Plaintiffs, a class of persons who purchased the common stock of defendant, NeoPharm, Inc. ("NeoPharm"), between the dates of October 31, 2001 and April 19, 2002 ("the class period"), alleging that NeoPharm, John N. Kapoor ("Kapoor"),[1] James M. Hussey ("Hussey"), and Imran Ahmad ("Ahmad") (collectively "defendants"), violated Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, by knowingly or recklessly making false and misleading statements regarding NeoPharm's experimental drug Liposome Encapsulated Paclitaxel ("LEP"). Plaintiffs also maintain that Hussey and Ahmad, acting as control persons, violated § 20(a) of the Exchange Act, 18 U.S.C. § 78t(a). Defendants have moved for summary judgment and to exclude the expert testimony of Bjorn I. Steinholt. For the reasons set forth below, defendants' motion for summary judgment [165] will be granted in part and denied in part. Defendants' motion to exclude [162] will be denied with leave to raise any challenges to his methodology in a motion in *limine* prior to trial.

[1] Kapoor was dismissed from the suit in February 2003. *See* Dkt. No. 45.

RELEVANT FACTS

NeoPharm is a biopharmaceutical company engaged in the research, development, and commercialization of drugs for the treatment of various forms of cancer. At all relevant times, Hussey was NeoPharm's President, Chief Executive Officer, and Director; Ahmad was NeoPharm's Vice President of Research and Development and Chief Scientific Officer.

Prior to the start of the class period, NeoPharm publicly represented that LEP was a potentially revolutionary method of administering the anti-cancer drug paclitaxel. Paclitaxel is marketed by Bristol-Myers Squibb Company under the trade name "Taxol®" and is used to treat a number of cancers, including breast and lung cancer. Despite paclitaxel's wide use and its anti-tumor characteristics, its effectiveness has been limited both by side effects, such as nausea, vomiting, hair loss and nerve and muscle pain, and by a long infusion time. Because of the chemical characteristics of paclitaxel, it cannot be introduced into the body unless it is first formulated in a toxic mixture of castor oil and ethanol, which requires premedication of the patient. LEP delivery consists of encapsulating paclitaxel in a liposome.[2] LEP does not require administration with castor oil and ethanol, thus reducing the need for premedication.

On February 19, 1999, NeoPharm entered into a worldwide collaborative relationship with Pharmacia & Upjohn Company ("Pharmacia") to develop and commercialize two products, one of which was LEP[3] (the "Pharmacia Agreement"). At that time, LEP was NeoPharm's lead product in development. Under the Pharmacia Agreement, Pharmacia obtained exclusive rights

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[2] Liposomes are "microscopic spheres composed of lipid (or fat) membranes." Feb. 7, 2003 Mem. Op. & Order at 6 n.3. (Dkt. No. 45).

[3] The other product involved in the licensing agreement is "liposome encapsulated doxorubicin" ("LED"). Defs.' Ex. 45 ¶ 1.24.

to develop and market LEP throughout the world and assumed responsibility for, and the costs associated with, the clinical development and regulatory filings for LEP. Further, neither NeoPharm nor Pharmacia was able to make public announcements regarding the development of LEP without the prior written consent of the other party, unless the disclosure was mandated by law. Defs.' SoF ¶ 2; Ex. 45 to Defs.' Appendix of Evidence ("Defs.' Ex."). No joint development committee between NeoPharm and Pharmacia was formed.[4] Rather, NeoPharm was to receive status updates regarding the progress Pharmacia had made in developing LEP. Defs.' SoF ¶ 3. Pharmacia's and NeoPharm's licensing arrangement was discussed in pre-class period analyst reports, as well as NeoPharm's own SEC filings, which indicated that its lack of control over LEP development was a significant risk factor. Defs.' SoF ¶¶ 5, 6. The analyst reports warned that Pharmacia might not be as aggressive regarding the development timelines as a biotechnology company would be. *Id.* ¶ 5. Consequently, Neopharm stock was rated as "high risk" and "speculative." *Id.* ¶ 7.

I. Clinical Trials Conducted by Pharmacia from August 2000 to July 2001

Pharmacia's initial clinical development plan[5] was two-pronged: (1) to run accelerated

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[4] Pharmacia's internal supervision over the development of LEP appears to have consisted of an LEP development team that reported to and was overseen by Pharmacia's Oncology Development Committee (referred to in the text as "ODC").

[5] The FDA regulates the development of new drugs and requires that any company seeking to introduce a new drug into the market complete clinical trials. The Seventh Circuit has explained,

> All clinical cancer trials occur in four phases. In Phase I the new medical procedure is tried out on human subjects for the first time, the aim being to determine the subject's maximum tolerance for a drug. In Phase II, therapies which have successfully passed Phase I are given to a larger group of individuals to determine if the procedure is efficacious for treatment of the disease. Phase III involves randomized clinical trials in which some patients receive the experimental treatment and others receive the conventional, nonexperimental treatment; the responses of the two groups are documented, analyzed and compared to assess the efficacy of the experimental treatment

Phase II clinical trials in esophageal, gastric and bladder cancers, sometimes referred to by the parties as "orphan cancers,"[6] for which the use of Taxol® was not FDA approved, and (2) to run Phase II clinical trials in breast and lung cancers, sometimes referred to by the parties as "key oncology indications,"[7] for which the use of Taxol® was FDA approved. Defs.' SoF ¶ 8. Because of the incentives under the Orphan Drug Act, Pharmacia's goal was to receive accelerated approval of LEP for orphan cancers. Pharmacia also wanted to receive FDA approval for a non-inferiority comparison to Taxol® for breast cancer.[8] Pls.' SoF ¶ 8.

In the third-quarter of 2000, Pharmacia commenced Phase II clinical trials for orphan cancers using a different formulation of LEP than had been developed by NeoPharm. Pls.' SoF ¶

> as compared with conventional treatments. Phase IV occurs after the drug is approved by the Food and Drug Administration and is to determine whether the drug is effective in other settings.

Smith v. *Office of Civilian Health & Med. Program of the Uniformed Servs*., 97 F.3d 950, 953 n.4 (7th Cir. 1996) (citations omitted).

[6] Esophageal, gastric and bladder cancers are referred to as "orphan cancers" because they are considered rare and often do not attract the necessary funding to advance treatment and drug development. 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 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).

[7] Although Taxol® was approved for the treatment of breast and lung cancers, because they are more common, they represented a far larger potential market for LEP than the orphan cancers for which Taxol® had not been approved. Defs.' SoF ¶ 9.

[8] A noninferiority comparison of LEP to Taxol® would mean that Pharmacia had to show the FDA that LEP was not less-effective than Taxol®. *See* Deposition of Christopher Bowden 74:1-9, Aug. 29, 2007 (referred to in the text as "Bowden Dep."). After meeting with the FDA in December 2000, Pharmacia revised its clinical development plan to conduct a superiority comparison with Taxol® in breast cancers. Pls.' SoF ¶ 5.

10. The LEP developed by NeoPharm was sonicated[9] ("LEP-s"); the LEP used by Pharmacia in the Phase II orphan cancer clinical trials was not sonicated ("LEP-ns"). *Id*. Pharmacia created LEP-ns because sonication produced a high variability in the content of non-encapsulated paclitaxel. Ex. 124 to Decl. of Steven W. Pepich (hereinafter "Pls.' Ex."). By eliminating sonication, Pharmacia believed that the drug would be easier to reproduce and therefore be more commercially viable. Defs.' Ex. 47. Pharmacia informed NeoPharm that the formulations were pharmaceutical equivalents, disclosing only that their new method of preparation eliminated sonication and added the organic compound "mannitol." Defs.' SoF ¶¶ 11, 13. At the time Pharmacia decided to use LEP-ns in its clinical trials, neither NeoPharm nor Pharmacia believed that the differences between the formulations were material. *See* Pls.' Resp. to Defs.' SoF ¶ 11. Accordingly, Pharmacia based the doses of LEP-ns given in the Phase II orphan cancer trials on the "maximum tolerated dose," or "MTD," obtained in Phase I trials for LEP-s.[10] Pls.' Resp. to Defs.' SoF ¶ 11; Bowden Dep. 136:19-137:14, 142:12-143:15. Nevertheless, at the same time Pharmacia commenced Phase II trials, it also commenced Phase I trials of LEP-ns to determine, among other things, whether its MTD was higher than that of LEP-s.

NeoPharm began receiving status updates on the clinical trials in February 2001. On

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[9] Sonication is defined as "[t]he process of dispersing, disrupting or inactivating biological materials, such as viruses, by the use of sound-wave energy." The American Heritage Stedman's Medical Dictionary, *available at* http://dictionary.reference.com/browse/sonication.

[10] Phase I usually determines the MTD, which is the highest dosage of a drug that patients can safely tolerate. It is established by discovering a patient's "dose limiting toxicity" ("DLT"), which is the dose at which side effects are severe enough to prevent further increase in dosage. *See* Understanding the Language of Clinical Trials, *available at* http://www.canceralternatives.mednet.ucla.edu/under.html. Thus. the MTD is the next lowest dose from the DLT.

February 5, 2001, Pharmacia emailed NeoPharm its January 2001 Monthly Update, reproduced in relevant part below:

Trial	Indication	Status	Comments
001	Phase I	1 patient ongoing, 90mg/m^2	- Enrollment @ 250 mg/m^2 open - Additional site initiated 11/28 (Marin Oncology)
005	2nd line Gastric Phase II	TBD	- No objective responses reported
006	2nd line Esophagus Phase II	TBD	- No objective responses reported
007	2nd line Bladder Phase II	TBD	
008	2nd line Gastric Phase II		1 patient has completed 6 cycles with stable disease
009	2nd line Esophagus Phase II		
010	2nd line Bladder Phase II		

Pls.' Ex. 18.

On March 14, 2001, Pharmacia emailed NeoPharm its February 2001 Monthly Update, reproduced in relevant part below:

Trial	Indication	Status	Comments
001	Phase I	1 patient ongoing, 90mg/m^2	
017	Phase I (weekly)		- No significant toxicity
005	2nd line Gastric Phase II		- No objective responses reported
006	2nd line Esophagus Phase II		- No objective responses reported

			- Enrollment stopped - Trial to be closed due to 1st stopping rule
007	2nd line Bladder Phase II	- 1st pt. died, sepsis neutropenia, related to LEP	
008	2nd line Gastric Phase II		1 patient has completed 6 cycles with stable disease
009	2nd line Esophagus Phase II		
010	2nd line Bladder Phase II	- Pt off-study for PD	

Pls.' Ex. 19.[11]

On April 13, 2001, Pharmacia emailed NeoPharm its March 2001 Monthly Update, reproduced in relevant part below:

Trial	Indication	Comments
001	Phase I	- 1 patient ongoing, 90mg/m^2 - 3rd cite to be added by the end of April
017	Phase I (weekly)	- No significant toxicity
005	2nd line Gastric Phase II	- No objective responses reported
006	2nd line Esophagus Phase II	- No objective responses reported (7 SD as best response) - Enrollment stopped - Trial to be closed due to 1st stopping rule
007	2nd line Bladder Phase II	- 1st pt. died, sepsis neutropenia, related to LEP
008	2nd line Gastric	- 1 patient has completed 6 cycles with stable disease

[11] The first stopping rule referred to in the comments section of trial 006 in both the February and March status updates means that the patients enrolled in that trial did not exhibit enough of a response in the first stage to move to the second. *See* Bowden Dep. 68:8-15.

	Phase II	- No objective responses reported
009	2nd line Esophagus Phase II	
010	2nd line Bladder Phase II	

Pls.' Ex. 20.

On June 5, 2001, Pharmacia emailed NeoPharm its May 2001 Monthly Update, reproduced in relevant part below:

Trial	Indication	Comments
001	Phase I	- 1 patient ongoing, 90mg/m^2
017	Phase I (weekly)	- No significant toxicity - 1 replaced because of early progression
005	2nd line Gastric Phase II	- study closeout activities ongoing
006	2nd line Esophagus Phase II	
007	2nd line Bladder Phase II	
008	2nd line Gastric Phase II	
009	2nd line Esophagus Phase II	
010	2nd line Bladder Phase II	

Pls.' Ex. 21. Hussey testified that after receiving the May 2001 Monthly Update he was "concerned enough to say let's have a meeting" to Pharmacia, but that he was not "particularly concern[ed] . . . about their commitment" to the development of LEP. Deposition of James

Hussey, 135:12-18, June 27, 2007 ("Hussey Dep.").

II. Events Leading Up to the Class Period: July 30, 2001 to October 31, 2001

A. July 30, 2001 Meeting between NeoPharm and Pharmacia

On July 30, 2001, Pharmacia and NeoPharm held a meeting to discuss the progress of the clinical trials. Pharmacia gave a Powerpoint presentation (Pls.' Ex. 26) stating that it closed the Phase II orphan cancer trials because the data collected (1) provided no support for accelerated approval, and (2) showed that patients with gastric, bladder and esophageal cancers responded better to Taxol® than LEP.[12] Pls.' Ex. 26 at 40, 58; Defs.' SoF ¶ 17 & Pls.' Resp. thereto. Possible explanations for the unsuccessful results discussed at the meeting were that (1) the patient population on which LEP was tested was too sick and/or resistant to the drug; (2) the LEP dosage administered was too low; and (3) LEP was ineffective at delivering paclitaxel to the tumor site. Defs.' SoF ¶ 17 & Pls.' Resp. thereto; Pls.' Ex. 121 at 3. The presentation detailed Pharmacia's new clinical development plan, which shifted the focus of LEP development to a superiority study of breast and small cell lung cancers.[13] Pls.' Ex. 26 at 58-69.

Although the MTD for LEP-ns had not yet been established, Pls.' SoF ¶ 13, Pharmacia provided estimations for the completion of the clinical studies for breast and small cell lung cancers. Pharmacia estimated that the Phase II clinical trials for breast cancer would begin in fourth-quarter 2001 or first-quarter 2002 with a target filing date of third-quarter 2006. Pls.' Ex.

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[12] Although Taxol® was not approved by the FDA as a treatment for bladder, esophageal or gastric cancers, published data were available indicating its efficacy.

[13] Pharmacia informed NeoPharm that its original goal of conducting a non-inferiority study was no longer viable based on the outcome of its meeting with the FDA. *See* Pls.' Ex. 26 at 52-58. Accordingly, Pharmacia decided to conduct a superiority study, *i.e.*, LEP's efficacy would have to be demonstrated to be significantly superior to Taxol®'s to obtain FDA approval.

26 at 63, 66, 69. One slide indicated that, based on the assumption that the MTD had been established by mid-third-quarter 2001 (mid-August 2001), Phase II breast cancer trials could begin in fourth-quarter 2001 (October to December 2001). *Id.* at 63. The Phase II trials in small cell lung cancer were estimated to begin in fourth-quarter 2001 or second-quarter 2002 (between October 2001 and June 2002) with a target filing date of second-quarter 2004. *Id*. at 66-67, 69.

The minutes from the July 2001 meeting reflect that NeoPharm and Pharmacia discussed, *inter alia*, (1) the different levels of toxicity experienced with LEP-s and LEP-ns, (2) the "potential marketing advantages" of LEP's long terminal half life, which acted like a continuous infusion of Taxol®; and (3) Pharmacia performing a comparison study of LEP vs. Taxol®, which Pharmacia agreed would be useful "if LEP proves to be sufficiently active in the presently planned Phase II." Pls.' Ex. 25. After the July 2001 meeting, NeoPharm "continued to believe that LEP was effective and that [NeoPharm and Pharmacia] were on track to register the drug with the FDA." Hussey Decl. ¶ 3, attached as Defs.' Ex. 83; *see also* Deposition of Donald H. Marks, M.D. 256:25-258:16, Jan. 30, 2008, attached as Defs.' Ex. 6.

B. NeoPharm's August 7, 2001 Conference Call with Investors

On August 7, 2001 NeoPharm held a conference call with investors. During the call Jeffrey Sherman[14] outlined Pharmacia's shift from developing LEP as a treatment for orphan cancers to one for breast and lung cancers. He further stated,

> We're pretty comfortable saying that we believe the breast and lung studies will begin by the end of the year early next year. . . the actual first enrolled patient should be in that time frame. . . . The breast and lung were selected versus other types of tumors based upon the current regulatory environment . . . . [They] were viewed as a more safe, less risky approval strategy by Pharmacia, their spending

[14] Sherman was the head of clinical development at NeoPharm.

> on the program has been exceptional and I think that they are on the right track and as I'll say to everybody it's extremely difficult to predict when the product maybe [sic] approved. The original dates that were I think published were filing in ['']03 and approval in ['']04. We have tried to give guidance this year that with the current FDA regulatory environment there is going to be in our estimation some risk[,] if not[] pretty high risk[,] there's just going to be some extension of those dates in terms of approval, but that Pharmacia strategy which we fully concur with of breast and lung is we believe the right strategy for approval.

Pls.' Ex. 162 at 5-6. During the question and answer period of the call, the following responses were given by Hussey:

> [Question:] Jim, it struck me as odd that you would talk about FDA in two years hence in terms of having problems. I think it's kind of premature, because we don't have the commissioner right now and things could be entirely different in six months unless, Upjohn is having a problem. Can you just address that?
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> JAMES HUSSEY: . . . [F]irst of all they are moving ahead very rapidly in terms of the studies, so there is not so much [a] per se problem . . . . The issue is trying to give guidance . . . [Y]our point's well taken[, which is that the regulatory] environment in 12 months[] could look totally different . . . . Once the FDA commissioner is named, I think you'll have a much clearer understanding of what's going to happen at FDA. But we just feel it's prudent for the investor to understand that the timeline and dates are just a bit more at risk until that's clarified. Now, if it's clarified and you begin to get very clear signals from FDA that they are back in approval mode, then I think it makes it – you feel more comfortable [in] effect saying that maybe that timelines may not change as much.
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> * * * * *
>
> [Question:] When you talk about a possible push out of whatever the schedule was that you had in 1999. If you look at the original timeline that . . . [had] led to that schedule, where are you on [the] net timeline right now compared to where you would have hoped to have been? In other words[,] . . . is the company or is the clinical development in any, somewhat behind schedule just based on what you had hoped to achieve.
>
> JAMES HUSSEY: . . . So if you think about it, if you would have started with the original strategy, which was [to] . . . go against, what I'd call, atypical tumors for third line kind of treatment, that's what was already done. In a new FDA environment, in a new changed direction from FDA, you start a different set of studies at the end of this year, you're looking at well maybe 12 or 14 months difference.

Id. at 8-12.

An August 8, 2001 Report issued by Business & Company Resource Center reflected the disclosure in the shift in LEP development from orphan cancers to breast and lung cancer, stated that pivotal LEP trials in breast and lung cancer would begin by year end and reflected that the launch date for LEP would be pushed back from late 2003 to early 2005. Defs.' Ex. 71.

III. Events from October 31, 2001, the Beginning of the Class Period, to the January 14, 2002 Meeting

A. NeoPharm's October 31, 2001 Press Release

On October 31, 2001, NeoPharm issued a press release regarding the LEP test results from the first quarter of 2001:

> NeoPharm today announced that clinical data for liposome encapsulated paclitaxel (LEP) were presented at the AACR-NCI-EORTC meeting in Miami, Florida on Tuesday. In the study, LEP is administered weekly for six weeks using an intravenous infusion . . . . LEP is being developed by Pharmacia Corporation under a licensing agreement with NeoPharm.
>
> "In the Pharmacia study involving weekly dosing of LEP, an extended terminal half-life was observed," said Imran Ahmad, Chief Scientific Officer of NeoPharm. "This is a significant improvement because more paclitaxel appears to [be] available to attack tumors over the six week administration schedule."

Defs.' Ex. 75. The press release contained a link to an abstract presented by Pharmacia on October 25, 2001.[15]

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[15] On October 25, 2001, Pharmacia presented an abstract at the American Association for Cancer Research ("AACR") regarding LEP. In addition to technical information regarding dose levels, it stated:

> As already observed in blood samples, the terminal half life of free paclitaxel was long and ranged between 70 and 760h. The terminal half life of both free and total paclitaxel was considerably longer than paclitaxel given in Cremophor El (Taxol®). Patient accrual continues and so far, no MTD has been reached. Dose escalation and PK analysis are ongoing.

Defs.' Ex. 18. The abstract was available to the public through the AACR's website.

B. January 11, 2002 Downgrade of NeoPharm's Stock

On January 11, 2002, an analyst for UBS Warburg called Hussey and asked him to comment about perceived problems with Pharmacia's LEP development program. Defs.' SoF ¶ 37. Specifically, the analyst inquired as to whether the Phase III trials for LEP would be delayed. Hussey Dep. 262:14-263:6. Hussey stated that Pharmacia had not updated him to that effect and that he had no knowledge. *Id.*

Later that day, UBS Warburg issued an analyst report downgrading NeoPharm's stock from a buy to hold "based on increasing concern regarding the timeline for Phase III development for the company's lead product LEP." Defs.' Ex. 73. The press release stated:

> Recall that the Phase III program was expected to commence in 4Q01. We believe that the perceived delay in initiating a Phase III trial introduces some degree of uncertainty as to Pharmacia's ability to move forward with the product rapidly. Discussion with senior management did not serve to allay these concerns.
>
> As a result, we believe that a Hold rating is most appropriate to reflect our increased concern. At present we prefer to take a wait and see approach until we gain further clarity into Pharmacia's development plans for the LEP. While we continue to believe that this product has a good likelihood of reaching the market, we are concerned that a delay in its time to market could adversely impact its market potential.

Id. The report explained that the market for paclitaxel alternatives was becoming increasingly crowded and, given that competition, "the time to market could have a significant impact on a product's market potential." *Id*. Later that day, Reuters reported that NeoPharm shares had dropped $3.75, or 16.09%, to $19.55 in afternoon trading in response to the concerns over the delay in LEP development. Defs.' Ex. 76. As requested by the defendants, the court takes judicial notice that NeoPharm stock closed at $23.30 on Thursday, January 10, at $20.05 on

January 11, and at $19.64 on January 14.[16] The parties agree that this is a statistically significant decline. Pls.' SoF ¶ 27 & Defs.' Resp. thereto.

Hussey testified that, after speaking with the analyst, "I was mad. I mean, I was like what is going on, and first of all, if they had made that decision and they had leaked that . . . without telling us, that would have made us and did make us very mad, right." *Id*. 265:13-19. Lawrence Kenyon, NeoPharm's Chief Financial Officer and Corporate Secretary, testified that,

> [T]he information we were getting was that we weren't talking about some slight delay, that when the Phase III was going to start, that there was something bigger going on where Pharmacia may not be interested and . . . we had received no information like that, and the result of the – the call was that we couldn't allay the concerns of the analysts. . . . [W]hat Jim was upset about that I recall most at the time was . . . hearing this from a third-party outsider who isn't related to Pharmacia in any way and. . . not hearing it from your partner. We would have expected to hear that already.

Deposition of Lawrence Kenyon, 99:19-100:16, July 31, 2007.

After confirming that no one at NeoPharm had been informed that Pharmacia intended to delay the Phase III trials, Hussey sent the following email to Gabe Leung[17]:

> I wanted to let you know UBS Warburg downgraded NeoPharm stock today over the perceived lack of progress in the LEP clinical trials by Pharmacia. The note from UBS Warburg is available on their website. Out company lost over $100 million of market valuation over this downgrade. Warburg explained to us that Wall Street viewed the partnership with Pharmacia as a major liability for us given the lack of progress in the clinical trials. The pace of the clinical trials is unsatisfactory to NeoPharm. Our chairman and Board are quite upset and wished to relay their complete dissatisfaction at the job done by Pharmacia.
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> Areas of gravest concern:
> 1) Seeming lack of progress in the clinic with LEP

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[16] *See* Yahoo! Finance, NeoPharm, Inc. (NEOL), Historical Prices, *available at* http://finance.yahoo.com/q?s=neol. Unless otherwise noted, all prices of NeoPharm stock stated in this section were obtained from this source.

[17] Leung was Pharmacia's Senior Vice President for Global Management.

> 2) L[a]ck of clear communication from [Pharmacia] about the pending trials
> 3) The lack of communication from [Pharmacia] about the program to Wall Street
> 4) The lack of progress on LED
>
> We are ready to discuss these issues on Monday. There was a time when I believed the licensing agreement was in both parties interest for LEP and LED. I no longer believe that and feel the need to share this with you personally before our meeting on Monday.
>
> We are considering all our options at this point and are extremely unhappy with [Pharmacia]. We do not believe you have been acting like a good partner for NeoPharm.

Defs.' Ex. 66. Hussey testified that he wrote the email because he felt "blindsided" and was "mad as hell." Hussey Dep. 271:12-272:6; 278:17-19.

After Hussey emailed Gabe Leung, he testified that he received summary information regarding the Phase I studies in anticipation of NeoPharm's and Pharmacia's meeting scheduled for Monday, January 14, 2002. Hussey Dep. 279:7-281:6; Defs.' Ex. 60. The summary information stated that the data collected by Pharmacia indicated . . . "exposure to free paclitaxel and the corresponding tumor inhibition is higher with LEP-s than LEP-ns. The fact that significantly higher doses of LEP-ns or LEP-s must be given to achieve the same antitumor effect as Taxol-m suggest[s] that liposome encapsulation of paclitaxel deliver[s] *free* paclitaxel to tumor tissues less effectively." Defs.' Ex. 60 at 6. The summary information further stated that two Phase I studies, trial numbers 001 and 017, were ongoing, that two patients had experienced a DLT and that the studies were expanding to more patients. *Id*. at 8, 13. The preclinical information contained in these materials was the first preclinical information NeoPharm had received since the July 30, 2001 meeting. Defs.' SoF ¶ 41. The materials received by NeoPharm prior to the January 14 meeting did not state that the Phase III start date would be delayed.

C. January 14, 2002 Meeting Between Pharmacia and NeoPharm

At the meeting, Pharmacia gave a Powerpoint presentation listing three objectives: (1) to review the most recent data including preclinical data on efficacy, pharmacy data on LEP-ns and LEP-s, and clinical data on Phase I; (2) to agree on the interpretation and implication of the reviewed data; and (3) to discuss key issues going forward. Defs.' Ex. 61 at 3. Slides from the presentation indicated that the particle size of LEP-ns was larger than LEP-s and that LEP-ns tended to accumulate in the liver and spleen. Defs.' SoF ¶¶ 43-44. NeoPharm scientists hypothesized that the elimination of sonication and the addition of mannitol may have caused LEP to have varying particle sizes upon reconstitution. *Id.* ¶ 45. They further surmised that the larger particle size of LEP-ns was causing its accumulation in the liver and spleen. *Id.*

After the data were presented, Hussey met with Gabe Leung and John McBride, head of Pharmacia's Oncology Licensing Department. Hussey "was angry and indicated that [Pharmacia] should have known that it was inappropriate to have clinically tested a liposomal formulation comprised of such large particles and that doing so allowed competitive paclitaxel projects to catch up to LEP. He further indicated that he would discuss this matter with his board." Defs.' Ex. 52 at NEOPH 071089.

The minutes from the meeting list the following as "Action Items":

- Pharmacia will provide NeoPharm with:

    1. Analytical methods used for PK (total and free paclitaxel) analysis including details of centrifugation procedures
    2. Experimental conditions for xenographic and ortotopic tumor growth inhibition
    3. Paclitaxel, cardiolipin and phosphatidyl choline supplies for development of a new LEP formulation. Imran Ahmad will send correspondence to Franco Rutili specifying the quantity of materials needed for development of the new LEP formulation.

4. LEP-s and LEP-ns for analysis
5. Hardcopy of slides presented for Gianfranco Rutili
6. LEP batch specifications; batch approval/passing criteria

- NeoPharm will proceed immediately with development of the new LEP formulation (timeline approx. 5 months); two 1,000 vial batches are foreseen.
- NeoPharm to conduct preclinical studies on the new formulation
- Obtain minutes of FDA's July '01 meeting on liposome-based therapy and distribute to LEP team and oncology department management
- Initiate monthly meetings (1 hour teleconference) between Pharmacia and NeoPharm
- Plan for a joint team meeting (Pharmacia and NeoPharm) later in the Spring of 2002 to discuss tentative development plan for the new LEP formulation

Defs.' Ex. 24 at NEOPH 068040-41. The parties do not dispute that NeoPharm worked actively on the new formulation, referred to as LEP-ETU, after the January 14 meeting. Defs.' SoF ¶ 56.

In follow-up correspondence, NeoPharm communicated to Pharmacia that based upon its data, further trials of LEP-ns were unlikely to be successful and Pharmacia communicated to NeoPharm that it would no longer pursue development of the LEP-ns. Pls.' Exs. 34, 35. Bowden testified that, after the meeting, both companies were "interested in figuring out a way to go forward with LEP," Bowden Dep. 245:22-246:9, and that Pharmacia remained fully committed to the development of LEP. *Id*. 247:13-16.

III. Events from January 15, 2002 to April 19, 2002, the End of the Class Period

A. NeoPharm's January 15, 2002 Press Release

On January 15, 2002, NeoPharm issued a press release stating,

> NeoPharm, Inc. (NASDAQ National Market: NEOL) announced today that it met with senior officials of Pharmacia (NYSE: Pharmacia) on Monday, January 13, 2002 regarding the LEP (Liposomal Encapsulated Paclitaxel) development program. Following that meeting, Pharmacia officials expressed the following points to NeoPharm officials regarding the licensing agreement with NeoPharm:
>
> 1) Pharmacia remains fully committed to the development of LEP.
> 2) Pharmacia is interested in exploring the possibility of licensing other products in the NeoPharm portfolio.
>
> Pharmacia, under a licensing agreement with NeoPharm, currently has all responsibility for development of LEP. As a result, NeoPharm is unable to confirm the clinical development timetable for LEP at this time.

Defs.' Ex. 26. The court takes judicial notice that NeoPharm stock closed at $18.05 on January 15, 2002.

B. NeoPharm's Statements at the February 11, 2002 Analyst Forum

On February 11, 2002, Hussey spoke at the Wall Street Analyst Forum in New York, which was broadcast on the Internet. Hussey stated that "LEP and LED are in Phase II/III with our partner Pharmacia" and discussed its advantages over Taxol®. Defs.' Ex. 28 at 2. During the question and answer period, the following exchange occurred:

> Audience: You mentioned in a previous meeting and also there has been some publicity about some slowdown with Pharmacia. . . . [T]his leads to the question [about] the milestone payment schedule. Has that been slowed down significantly too? When is . . . [Pharmacia expected] to make milestone payments?
>
> Hussey: Well, clearly the milestone payments were paid along with the clinical program and everything else. We're meeting hopefully shortly with Pharmacia to talk about the new timing. We are assisting them. They had made a change in the product which they felt was not a big deal. It ended up for them being a big deal. They have brought us in now to fix it. We're hopeful we'll be able to fix that in a rapid fashion and I think in the next 60 days we'll have a better idea of timing. So I just would like to defer if I could to maybe 60 days from now we'll be able to

> address the timing question as to what it means for the milestones and everything else.

Id. at 6. The court takes judicial notice that NeoPharm stock increased from $14.98 at close on February 11, 2002 to $17.79 at close on February 12, 2002.

C. NeoPharm's and Pharmacia's Pre-Arbitration Discussions: January 31, 2002 to March 6, 2002

On January 31, 2002, NeoPharm's Board of Directors held a meeting during which they discussed pursuing legal action against Pharmacia. The presentation stated that Pharmacia had misrepresented the LEP-ns formulation, particularly its particle size, and that "[a]ny reasonable scientist, consulting the literature would have known the importance of particle size in liposome formulation." Pls.' Ex. 40 at NEOPH 004896. NeoPharm estimated that it had been damaged in the amount of "approximately $1 billion, using Pharmacia's original timing and revenue estimates, not including the impact on our own product development nor punitive damages." *Id*. The minutes from that meeting reflect that NeoPharm's Board of Directors authorized management to provide Pharmacia with notice that they wished to "resolve the Company's current disputes with Pharmacia through good faith negotiation." Pls.' Ex. 39 at NEOPH 079834. In the event negotiations failed, the Board simultaneously authorized NeoPharm to resort to arbitration. *Id*. A presentation prepared by NeoPharm in early February 2002 for pre-arbitration discussions with Pharmacia further states "[t]hree years after Agreement signed, LEP and LED are no closer to commercialization and are, in fact, a year away from Phase I completion." Pls.' Ex. 42 at NEOPH 87367. NeoPharm estimated that the projected launch of LEP would be delayed by several years, from 2003 to 2007, and posited that the delay had likely cost LEP its first mover advantage as a Taxol® alternative. Pls.' SoF ¶ 33; Pls.' Exs. 42 at

NEOPH 87369-70.

On March 5, 2002, Pharmacia and NeoPharm attended a pre-arbitation meeting. Larry Kenyon, Pharmacia's Chief Financial Officer, summarized Pharmacia's position as follows:

1. Despite representations made by Pharmacia in 1999, the commercial value of LEP is lower today.

2. Commercialization of the original sonicated LEP formula NeoPharm provided to Pharmacia was not feasible due to too much variability.

3. Since Pharmacia's non-sonicated formulation was not working, Pharmacia needs to restart the LEP development program.

4. NeoPharm appears to have a feasible non-sonicated formula and Pharmacia would like to continue to work with NeoPharm to develop LEP.

5. Pharmacia proposes to settle the dispute by making modifications to the current License Agreement (financial terms acceptable to Pharmacia were not disclosed).

Pls.' Ex. 45. Kenyon summarized NeoPharm's position as:

1. Pharmacia was aware of the LEP sonication requirement prior to signing the License Agreement, and Pharmacia was also aware of previous work conducted by NeoPharm to address any sonicated related issues with the LEP formulation. Pharmacia did not consult with NeoPharm on this issue after the License Agreement was signed in February 1999.

2. Pharmacia's own investigator's brochure for LEP . . . stated that Pharmacia was aware that the non-sonicated LEP formulation being used for Phase II was not equivalent to the sonicated LEP formulation used in Phase I, but the Phase II trials would continue as planned using the non-sonicated formulation without any further pre-clinical testing of the formulation.

3. The commercial potential of LEP will never be known since delays in the development program at Pharmacia have pushed back the projected launch of the product from 2003 to 2007, at the earliest, and this delay has likely cost LEP its first mover advantage in the endeavor to replace Taxol® with a more effective or less toxic taxane.

4. Any reasonable scientist would have conducted pre-clinical research on the new non-sonicated formula to characterize the differences versus the sonicated formula before beginning clinical studies. These pre-clinical studies would have shown that the non-sonicated formulation would not work.

Id.

At the March 5 meeting, NeoPharm and Pharmacia discussed a settlement wherein Pharmacia would make an investment in NeoPharm and license its future products. Pharmacia indicated, however, that its scientists were not convinced that the NeoLipid® liposome encapsulation system was effective in delivering drugs and would need to determine the system's viability before agreeing to such a settlement. The parties agreed to move quickly to attempt to achieve settlement prior to arbitration. *Id*.

On March 6, 2002, Hussey sent a letter to Leung reiterating NeoPharm's "issues and concerns." Defs.' Ex. 65. At the end of the letter Hussey stated that although "we felt some progress was made during the meeting toward reaching a settlement without resorting to arbitration, and NeoPharm remains committed to achieving a settlement," NeoPharm "was prepared to enter arbitration if a settlement can't be reached." *Id*. Hussey informed Leung that "[t]he good faith negotiating period with respect to NeoPharm's claim of breach expires on March 14, 2002." *Id*.

D. March 18, 2002 Press Release

On March 18, 2002, NeoPharm issued a press release entitled "NeoPharm Announces Fourth Quarter 2001 Financial Results," which states, in relevant part,

> NeoPharm's other products in clinical development, LEP (liposome encapsulated paclitaxel) and LED (liposome encapsulated doxorubicin), are currently in development at Pharmacia Corporation (NYSE: PHA) under a licensing agreement with NeoPharm. Phase I data on LEP was recently presented at the AACR-NCI-EORTC meeting in Miami, Florida, showing the extended terminal

> half-life of LEP using a weekly administration schedule. Copies of the abstract are available from the company upon request.

Pls.' Ex. 47.[18]

The same day, NeoPharm held a fourth quarter conference call and update with analysts. *See* Defs.' Ex. 74. During the call, NeoPharm stated that it had "discussed expanding the Pharmacia agreement beyond LEP and LED," *id*. at 3, but that he was "unable to provide any clarity on the timing." *Id*. at 5. When asked if there were an update on the timeline for LEP and LED, Hussey stated that they would discuss that "within the construct of the expanded agreement." *Id*. at 6. When asked whether NeoPharm had reformulated LEP in the ETU formulation, Hussey said "we want to just kind of keep that under the whole context of the Pharmacia discussions." *Id*. at 6-7.

E. NeoPharm's April 11, 2002 Filing

On April 11, 2002, NeoPharm filed its Form 10-K for the year ending December 31, 2001 with the SEC. The filing stated certain positive results of the Phase I/II clinical trials completed in April 2000 by Pharmacia, including that certain patients had experienced reduction of tumors or no tumor growth without the side effects commonly attributable to Taxol®.[19] Defs.' Ex. 30 at 8. The filing further stated:

> Currently, our licensee, Pharmacia, is responsible for the commercial development of LEP, including conducting clinical trials and working with the FDA to successfully commercialize the drug. As of the date of this filing, we are endeavoring to obtain definitive information on the development status of LEP

[18] The referenced meeting occurred on October 25, 2001.

[19] The parties agree that the clinical trials referenced involved LEP-s. Pls.' SoF ¶ 36 & Defs.' Resp. thereto. There is no evidence that either Pharmacia or NeoPharm planned to return to LEP-s development after the January 14 meeting. *See* Pls.' SoF ¶¶ 31, 32 & Defs.' Resp. thereto; Bowden Dep. 121:13-122-4; Deposition of Imran Ahmad 151:16-152:22, July 31, 2007.

> from Pharmacia. See "Collaborative Relationships and Licenses – Pharmacia License Agreement."

Id. Under "Collaborative Relationships and Licenses - Pharmacia License Agreement," the filing

states, in relevant part:

> In January 2002, Pharmacia informed us that the LEP and LED development program were experiencing delays. At the time of that meeting, Pharmacia was unable to determine when Phase II/III studies were expected to begin. We continue to work with Pharmacia to determine the development status of both LEP and LED, but as of the date of this filing, Pharmacia has not provided us with new target dates for starting Phase II/III clinical trials in these products.

Id. at 11.

F. NeoPharm's April 19, 2002 Press Release

On Friday, April 19, 2002, NeoPharm issued a press release entitled "NeoPharm Files for Arbitration of Dispute with Pharmacia," which stated, in relevant part:

> NeoPharm has filed for arbitration to resolve a dispute with Pharmacia concerning unnecessary delays in the development programs for LEP . . . . NeoPharm contends that Pharmacia failed in its duty under the License Agreement to use reasonable efforts to develop LEP and LED. NeoPharm further contends that Pharmacia breached its duty to consult with NeoPharm on the progress of the drug development program, and thereby impaired NeoPharm's ability to monitor the development. As a direct result of these failures by Pharmacia, NeoPharm asserts that is has sustained substantial damages.

Pls.' Ex. 50. NeoPharm further stated that although it "is not currently seeking a termination of the License Agreement as part of the arbitration," it had "determined that it is not in [its] best interests to move forward with Pharmacia on collaborations for any other compounds, at least not until [its] concerns with Pharmacia regrading LEP and LED are successfully resolved." *Id*.

NeoPharm shares closed at $20.41 on April 19. On Monday, April 22, they closed at $15.43 – a $4.68 drop, or more than 24 percent. Both plaintiffs' and defendants' experts agree

that this is a statistically significant decline. Pls.' SoF ¶ 40 & Defs.' Resp. thereto. Bloomberg, L.P. reported on the announcement, stating in relevant part that:

> "Investors have been patiently waiting for clarification on this since January," when NeoPharm said it discussed the development timeline with Pharmacia, said David Webber, a first Albany Corp. analyst who cut his rating today on NeoPharm to "neutral" from "buy."
>
> Pharmacia spokesman Paul Fitzhenry said LEP failed to show a benefit in studies Pharmacia conducted. The compound has been in the second of three stages of human testing generally required for regulatory approval since 2000, he said.

Pls.' Ex. 174, Attachment I.

LEGAL STANDARD

Summary judgment obviates the need for a trial where there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56©. To determine whether any genuine fact exists, the court must pierce the pleadings and assess the proof as presented in depositions, answers to interrogatories, admissions, and affidavits that are part of the record. Fed. R. Civ. P. 56© advisory committee's notes. The party seeking summary judgment bears the initial burden of proving there is no genuine issue of material fact. *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). In response, the non-moving party cannot rest on bare pleadings alone but must use the evidentiary tools listed above to designate specific material facts showing that there is a genuine issue for trial. *Id.* at 324; *Insolia* v. *Philip Morris Inc.*, 216 F.3d 596, 598 (7th Cir. 2000). A material fact must be outcome determinative under the governing law. *Insolia*, 216 F.3d at 598-99. Although a bare contention that an issue of fact exists is insufficient to create a factual dispute, *Bellaver* v. *Quanex Corp.*, 200 F.3d 485, 492 (7th Cir. 2000), the court must construe all facts in a light most favorable to the non-moving party as well as view all reasonable inferences

in that party's favor. *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986).

Northern District of Illinois Local Rule 56.1(a) requires the party seeking summary judgment to submit, among other things, a statement of material facts, which consists of short, numbered paragraphs and specific references within each paragraph to the affidavits, parts of the record, and other supporting materials relied upon to support the facts set forth in that paragraph. L.R. 56.1(a)(3). The non-moving party must then submit a concise response to the movant's statement of facts. *Id*.

ANALYSIS

Before reaching the merits of the defendants' motion for summary judgment, the court will address NeoPharm's contention that certain of plaintiffs' responses to defendants' Rule 56.1 Statement of Uncontested Facts do not comply with the local rule because they (1) are not concise; (2) fail to properly cite supporting evidence or any evidence; (3) mischaracterize the cited evidence; and (4) include additional information unrelated to the fact asserted by the defendants. Defs.' Reply at 11. The court is entitled to expect strict compliance with Local Rule 56.1 procedures. *Ammons* v. *Aramark Unif. Servs, Inc.*, 368 F.3d 809, 817 (7th Cir. 2004). A response may not consist solely of "purely argumentative denials," or "evasive denials that do not fairly meet the substance of the material facts asserted." *Am. Hardware Mfrs. Ass'n* v. *Reed Elsevier, Inc.*, No. 03 CV 9421, 2010 U.S. Dist. LEXIS 57, at *5-6 (N.D. Ill. Jan. 4, 2010) (quoting *Malec* v. *Sanford*, 191 F.R.D. 581, 584 (N.D. Ill. 2000), and *Bordelon* v. *Chi. Sch. Reform Bd. of Trustees*, 233 F.3d 524, 528 (7th Cir. 2000)); *see also Cady* v. *Sheahan*, 467 F.3d 1057, 1060 (7th Cir. 2006) (explaining that it is inappropriate to make legal arguments in Rule

56.1 statements and responses). The court may disregard such responses because it is not required to "'wade through improper denials and legal argument in search of a genuinely disputed fact.'" *Am. Hardware Mfrs. Ass'n*, 2010 U.S. Dist. LEXIS 57, at 5-6 (quoting *Bordelon*, 233 F.3d at 529). The court may also disregard or deem admitted statements that do not properly cite to the record. *See Smith* v. *Lamz*, 321 F.3d 680, 683 (7th Cir. 2003) ("[A] mere disagreement with the movant's asserted facts is inadequate if made without reference to specific supporting material."); *Cichon* v. *Exelon Generation Co., L.L.C.*, 401 F.3d 803, 809-10 (7th Cir. 2005) ("[A] district court does not abuse its discretion when, in imposing a penalty for a litigant's non-compliance with Local Rule 56.1, the court chooses to ignore and not consider the additional facts that a litigant has proposed"). While the court agrees with defendants that many of plaintiffs' responses to their Local Rule 56.1(a) statement of material facts are argumentative and contain improper denials, the court believes that these responses were prompted in part by defendants having favorably characterized, rather than plainly stated, several facts. Accordingly, the court has endeavored to determine what the undisputed evidence actually is by sifting through the fifty-one page document containing defendants' statements, plaintiffs' responses and defendants' replies and by directly examining the voluminous supporting evidence. To the extent possible, the court has disregarded certain non-compliant portions of plaintiffs' response, but declines to strike or deem admitted the paragraphs defendants place at issue.

I. NeoPharm's Alleged Violations of Section 10(b) and Rule 10b-5

Section 10(b) forbids the "use or employ[ment], in connection with the purchase or sale of any security . . . [,] any manipulative or deceptive device or contrivance in contravention of [Securities and Exchange Commission] rules and regulations." 15 U.S.C. § 78j(b). Rule 10b-5

makes it unlawful for any person "[t]o 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 light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5. The Supreme Court has ruled that when cases involve the purchases of securities in public securities markets, as they do here, the elements of a private damages action are

(1) a material misrepresentation (or omission);

(2) scienter, *i.e.*, wrongful state of mind;

(3) a connection with the purchase or sale of security;

(4) reliance, often referred to in cases involving public securities markets (fraud-on-the-market cases) as "transaction causation;"

(5) economic loss; and

(6) "loss causation," *i.e.*, a causal connection between the material misrepresentation and the loss.

Dura Pharms, Inc. v. *Broudo*, 544 U.S. 336, 341, 125 S. Ct. 1627, 161 L. Ed. 2d 577 (2005) (citations omitted).

Plaintiffs argue that five statements made during the class period were false or misleading: (1) NeoPharm's October 31, 2001 press release; (2) NeoPharm's January 15, 2002 press release, (3) Hussey's statements at the February 11, 2002 analyst forum; (4) NeoPharm's March 18, 2002 press release; and (5) NeoPharm's April 11, 2002 Form 10-K filing.[20] NeoPharm contends that, for all these statements, there is no genuine issue of material fact with respect to the first, second and sixth elements of plaintiffs' Section 10(b) claim, warranting the

[20] The court has dismissed plaintiffs' claims insofar as they were based on statements made in analysts' reports prior to January 12, 2002. *See* Feb. 7, 2003 Mem. Op. & Order at 21-22 (Dkt. No. 45).

grant of summary judgment in their favor. For analytical purposes, the court will separate these statements in two categories, those occurring before and after the January 14, 2002 meeting between NeoPharm and Pharmacia.

A. NeoPharm Statements from October 31, 2001 to January 14, 2002

Plaintiffs only seek to hold NeoPharm liable for one statement made prior to the January 14 meeting: the October 31, 2001 press release. Plaintiffs contend that after the August 7, 2001 investor conference, investors still believed that Phase II studies in breast and lung cancer would commence at the end of 2001 or the beginning of 2002, but that NeoPharm knew that this was untrue because no MTD had been established by that time and the clinical evidence available to NeoPharm "strongly indicated that the prior unsuccessful Phase II testing resulted from a fundamental flaw in LEP." Pls.' Mem. in Opp. at 10. Plaintiffs contend that NeoPharm had a duty to disclose such information when making positive statements about LEP's terminal half life. In their motion for summary judgment, defendants contend that the evidence shows they did not know, prior to the January 14 meeting, that LEP needed to be reformulated or that the Phase II breast and lung cancer trials would be delayed indefinitely. Defendants' point is well-taken because they cannot be liable for failing to disclose information of which they were unaware. There is no "fraud by hindsight." *See Asher* v. *Baxter*, 377 F.3d 727, 730 (7th Cir. 2004) ("[A]n unexpected turn of events cannot demonstrate a securities problem at all, as there cannot be 'fraud by hindsight.'" (quoting *Denny* v. *Barber*, 576 F.2d 465, 470 (2d Cir. 1978) (Friendly, J.))). In other words, "[a] party alleging securities fraud must show statements were false when made." *In re Metris Cos., Inc.*, 428 F. Supp. 2d 1004, 1011 (D. Minn. 2006) (citing *In re Navarre Corp., Sec. Litig.*, 299 F.3d 735, 742 (8th Cir. 2002)). Thus, as this court

explained in its previous opinion, the operative issue in determining whether the October 31 statement can be considered misleading is whether, at that time, "NeoPharm had knowledge that the Phase II trials were failing to such a great degree that the Phase I results would be affected, and that they were, for practical matters, back to the drawing board with respect to LEP development." Feb. 7, 2003 Mem. Op. & Order at 20 (Dkt. No. 45).

The evidence presented by NeoPharm shows that prior to January 14, 2002, it was unaware that LEP-ns was fundamentally flawed, would not be tested in Phase II trials and, therefore, that LEP had to be reformulated and development restarted from the preclinical stage. While the monthly updates received by NeoPharm for January, February, March and May 2001 showed that the Phase II orphan cancer trials were generating disappointing results and that the Phase I studies of LEP-ns had yet to generate a MTD, as of October 31, 2001, NeoPharm had not yet formed the opinion that this was due to a fundamental flaw (the large particle size) in the current formulation of LEP (LEP-ns). Rather, the evidence shows that the only difference of which NeoPharm was aware as between LEP-s and LEP-ns was the elimination of sonication, the addition of mannitol and that the same dose of the different formulations caused different levels of toxicity in patients. This is why NeoPharm and Pharmacia discussed several possible explanations of the clinical results at their July meeting, including that (a) the patients to which LEP-ns were given were too sick and/or resistant to the drug, (b) the dose was too low, and © LEP was ineffective at delivering paclitaxel to the tumor site. Notably, the possible explanations did not include the particle size of LEP or any problem specific to LEP-ns. Pharmacia's and NeoPharm's decision to quickly move forward with Phase II testing in breast and lung cancer – which had the potential to be more lucrative – in fourth-quarter 2001 or first-quarter 2002

despite the results of the orphan cancer trials is additional evidence that, as of October 31, 2001, defendants did not believe LEP-ns was fundamentally flawed and needed to be reformulated. This conclusion is buttressed by Hussey's surprised and angry reaction to (1) the downgrade of NeoPharm stock on January 11 based on the leaked information that there would be further delays in Pharmacia's LEP development – information that NeoPharm was neither able to confirm nor deny due to Pharmacia's failures to communicate – and (2) Pharmacia's disclosure at the January 14 meeting that LEP-ns was constituted of large particles – information that led NeoPharm to conclude that LEP-ns was ineffective because its particle size caused it to be trapped in patients livers and spleens.

Plaintiffs' argument that NeoPharm knew by October 31, 2001 that Phase II studies would not start within the fourth-quarter 2001 or first-quarter 2002 time frame conveyed to investors during the August 2001 investor conference call is largely based on one of the 73 slides in Pharmacia's presentation at the July 2001 meeting. That slide graphs an estimated LEP development timeline for breast cancer and indicates that, based on the assumption that the MTD for LEP-ns had been determined by mid-third-quarter 2001, Phase II studies in breast cancer would begin in fourth-quarter 2001. Plaintiffs argue that because NeoPharm knew, presumably via the Phase I updates they received in early October, that the MTD for LEP-ns had not been established by mid-third-quarter 2001, it also knew that Phase II testing for both breast and lung cancers was halted indefinitely. Plaintiffs' argument, however, assumes too much.

There is no evidence to support plaintiffs' contention that Pharmacia planned to abandon or even to indefinitely postpone all Phase II trials in both breast and lung cancer if no MTD had been established by mid-third quarter 2001. Rather, as the other slides from the presentation

indicate, Pharmacia planned on beginning Phase II trials anytime between October 2001 and March 2002 based on its assumption that the MTD would be established in time to do so.[21] Nor is there any evidence that NeoPharm viewed this plan as untenable; indeed, the results from the Phase II orphan trials indicated that two patients had experienced a DLT, a result that indicated that Pharmacia was getting closer to determining the MTD of LEP-ns.[22] Furthermore, plaintiffs do not argue, and nothing in evidence suggests, that Phase II trials could not have begun in first-quarter 2002, and therefore within the time frame disclosed to investors, if the MTD had been established in fourth-quarter 2001. As of October 31, 2001, two months remained in fourth-quarter 2001. Thus, plaintiffs have failed to come forward with evidence sufficient to show that, as of that date, NeoPharm knew (1) that Phase II trials could not or would not begin within the time frame previously disclosed to investors, or (2) that the current formulation of LEP was fundamentally flawed such that LEP needed to be reformulated and LEP development restarted from the preclinical stage.

As plaintiffs have failed to demonstrate a material issue of fact as to whether the October 31 press release was misleading at the time it was made, and consequently, whether it was made with the requisite scienter, summary judgment will be granted to defendants to the extent

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[21] Pharmacia's LEP project team did not make the internal recommendation to postpone the commencement of Phase II trials pending the completion of preclinical testing comparing LEP-ns and LEP-s until its November 5, 2001 ODC meeting. *See* Pls.' Ex. 124 at 9 ("The LEP project team recommends not to start the planned phase II program in breast and SCLC until scheduled preclinical studies . . .are completed (Jan 02)."). There is no evidence to indicate that NeoPharm was informed of this internal decision until the January 14 meeting.

[22] The MTD is the next lowest dose from the DLT. *See supra* at 5 n.10.

plaintiffs' claims are based on that statement.[23]

B. NeoPharm Statements from January 15, 2002 to April 19, 2002

The statements at issue during the period from January 15, 2002 to April 19, 2002 are (1) NeoPharm's January 15 press release; (2) Hussey's statements at the February 11 analyst forum; (3) NeoPharm's March 18 press release; and (4) NeoPharm's April 11 Form 10-K filing.

1. Materiality

Defendants argue that there is no evidence that they made material misrepresentations or omissions during this period because investors were aware that there would be delays in LEP development. The court interprets this contention as an argument that the omissions alleged by plaintiffs are not material. "[T]o fulfill the materiality requirement there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Basic Inc.* v. *Levinson*, 485 U.S. 224, 231-32, 108 S. Ct. 978, 99 L. Ed. 2d 194 (1988) (citation omitted) (internal quotation marks omitted). The Seventh Circuit has further explained that "the determination [of materiality] requires delicate assessments of the inferences a reasonable shareholder would draw from a given set of facts and the significance of those inferences to him, and these assessments are peculiarly ones for the trier of fact; thus a materiality determination is rarely appropriate at the summary judgment stage." *Marks* v. *CDW Computer Ctrs.*, 122 F.3d 363, 370 (7th Cir. 1997) (citations omitted) (internal quotation marks omitted); *see also Wehrenberg* v. *Fed. Signal Corp.*, No. 06 C 487, 2008 U.S. Dist. LEXIS 35311, at *17 (N.D. Ill.

[23] Because there is no evidence that the individual defendants were aware of the development delays or fundamental flaws in the LEP-ns formulation prior to January 14, 2002, they cannot be held liable as control persons for statements made prior to that date. *See infra* at 38-39.

Apr. 29, 2008) ("[S]ummary judgment is appropriate on the issue of materiality only if the information in question is so obviously unimportant to an investor, that reasonable minds cannot differ on the question." (collecting cases)). Courts in this district have noted that "materiality has been characterized as a mixed question of law and fact, and courts have admonished that only when the disclosures or omissions are so clearly unimportant that reasonable minds could not differ should the ultimate issue of materiality be decided as a matter of law." *Lincoln Nat'l Life Ins. Co.* v. *Donaldson, Lufkin & Jenrette*, 9 F. Supp. 2d 994, 1003 (N.D. Ill. 1998).

Prior to the January 14 meeting, both NeoPharm and investors had the same amount of information regarding the timeline for LEP development. As of August 7, 2001, both NeoPharm and investors knew that Phase II trials in breast and lung cancer were estimated to commence at the latest in first-quarter 2002, with a launch date of early 2005. And, on January 11, 2002, NeoPharm and investors simultaneously learned that further delays in LEP development were possible. After the January 14 meeting, however, NeoPharm was made aware of several facts which were not disclosed to investors prior to the end of the class period: (1) that LEP-ns was fundamentally flawed; (2) that there would be no Phase II/II testing of LEP-ns; (3) that LEP needed to be reformulated; and (4) that any further clinical trials would have to be restarted from the preclinical stage.[24] Further, these facts led NeoPharm to conclude that LEP had likely lost its first mover advantage as a Taxol competitor, substantially reducing its market value, and warranting legal action against Pharmacia. It is NeoPharm's touting of favorable news and data from LEP development while failing to disclose these facts which plaintiffs contend render the

[24] The undisputed evidence also establishes that neither NeoPharm nor Pharmacia planned to pursue the development LEP-s after the January 14 meeting.

statements at issue misleading. *See Schlifke* v. *Seafirst Corp.* 866 F.2d 935, 944 (7th Cir. 1989) (Rule 10b-5 proscribes "omissions that render affirmative statements misleading; thus, incomplete disclosures, or half-truths, implicate a duty to disclose whatever additional information is necessary to rectify the misleading statements." (citations omitted) (internal quotation marks omitted)). The court cannot find that, as a matter of law, the omission of the information identified by plaintiffs would be so unimportant to the investor that reasonable minds could not differ on the issue, particularly in this case, where defendants admit that LEP's time to market was the information about which investors were most concerned, Defs.' Reply at 5, and where the disclosure of such facts may have indicated, as it did to Hussey at the January 14 meeting, that LEP had likely lost its first mover advantage as a Taxol® alternative and, consequently, that its market value was substantially reduced. Accordingly, the court finds that a material issue of fact exists as to the issue of materiality.

To the extent defendants argue for the first time in reply that they had no duty to disclose the information which plaintiffs contend was omitted, this argument has been waived, *see Carter* v. *Tennant Co*., 383 F.3d 673, 678 (7th Cir. 2004) (arguments presented for the first time in reply are waived); but even if this argument were timely, it would still be unavailing. Defendants contend that "there is *no* duty to disclose adverse information revealed in drug trials until a pharmaceutical company had reached a *consensus* that the trial results are sufficiently serious and adverse as to 'threaten' the drug's 'commercial viability.'" Defs.' Reply at 7-8. In support of this contention they cite, *inter alia*, to *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998). In that case, the plaintiffs sought to hold a pharmaceutical company liable for failing to disclose reports of deaths related to one of its FDA-approved drugs. In ruling that the

pharmaceutical company had no duty to disclose the drug-related deaths at the time the statements at issue were made, the Second Circuit explained,

> Carter-Wallace's Form 10-K and its "Report to Shareholders" did not become materially misleading until Carter-Wallace had information that Felbatol had caused a statistically significant number of aplastic-anemia deaths and therefore had reason to believe that the commercial viability of [the drug] was threatened. Drug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by – rather than randomly associated with – use of the drugs and are sufficiently serious and frequent *to affect future earnings*.

Id. at 157 (citations omitted) (emphasis added). Because, at the time the statements at issue were made, the pharmaceutical company knew of only four of the ten deaths ultimately linked to its drug, the court determined that no inference of scienter was warranted. *See also Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (relying on *Carter-Wallace* in ruling that pharmaceutical company's withholding of inconclusive data could not be considered material because it did not provide "statistically significant evidence").

Defendants argue that because NeoPharm and Pharmacia never reached a consensus as to why the clinical trials of LEP-ns had failed – Pharmacia questioned whether NeoPharm's liposome encapsulation system was an effective method of delivering paclitaxel while NeoPharm hypothesized that the particle size of LEP-ns had rendered its otherwise effective method ineffective – NeoPharm had no duty to disclose the trials' negative results. Whether NeoPharm and Pharmacia reached a consensus as to why the clinical trials had failed, however, is irrelevant because plaintiffs do not contend that investors would have considered such information material. Rather, as defendants concede, investors were most concerned with information concerning LEP's time-to-market because it was a direct indicator of NeoPharm's *future earnings* – the more quickly LEP would be approved, the more likely it was to be profitable

because the market for Taxol® alternatives was becoming increasingly crowded. The undisputed evidence shows that NeoPharm and Pharmacia reached a consensus at the January 14 meeting that LEP-ns had failed, that LEP would have to be reformulated and that LEP development would have to be restarted from the preclinical stage.[25] It also clearly demonstrates that, as of that date, NeoPharm knew its future earnings would suffer significantly, hence NeoPharm's statement that "the commercial potential of LEP would never be known" and belief that it had been damaged in that amount of approximately $1 Billion. *See supra* at 19-20. Thus, NeoPharm cannot persuasively argue that it had no duty to disclose under the reasoning of *Carter-Tennant*.

2. Scienter

To establish scienter in the securities fraud context, the plaintiff must show that "the defendant acted with the intent to deceive, manipulate or defraud and was not merely negligent or that the defendant acted with reckless disregard for the truth of the material asserted, whether by commission or omission." *Ambrosino* v. *Rodman & Renshaw, Inc*. 972 F.2d 776, 788-89 (7th Cir. 1992) (citing *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185, 193, 214, 47 L. Ed. 2d 668, 96 S. Ct. 1375 (1976), and *Sundstrand Corp.* v. *Sun Chem. Corp.*, 553 F.2d 1033, 1044 (7th Cir. 1977)). As defendants acknowledge, "circumstantial evidence can be more than sufficient" to establish scienter. *Herman* & *Maclean* v. *Huddleston*, 459 U.S. 375, 390 n.2, 103 S. Ct. 683, 74 L. Ed. 2d 548 (1983); Defs.' Reply at 4.

Defendants contend that plaintiffs have produced no evidence of scienter and argue that

[25] *See, e.g.*, "Action Items" from the January 14 meeting indicating that LEP would need to be reformulated, that NeoPharm would develop a new LEP formulation in approximately five months, and that preclinical studies would have to begin at the preclinical stage, *supra* at 16-17.

NeoPharm did not know that LEP development would be indefinitely delayed until after the January 14 meeting and, upon learning that there would be indefinite delays, disclosed this information the next day. Defs.' Mem. in Supp. at 14. As discussed above, however, NeoPharm's statements after January 14 emphasized positive aspects of LEP formulations no longer in development and the possibility of expanded business with Pharmacia without disclosing that Phase II studies were halted, that LEP development would have to be restarted from the earliest stages, and that NeoPharm was considering taking legal action against Pharmacia. Because the circumstantial evidence produced by plaintiffs permits the inference that defendants intentionally concealed the extent of the problems with LEP development, the court concludes that a genuine issue of material fact exists as to scienter. *See SEC* v. *Roszak*, 495 F. Supp. 2d 875, 890 (N.D. Ill. 2007) (denying summary judgment for defendants where the undisputed facts permitted an inference that insider trading occurred); *Endo* v. *Albertine*, 863 F. Supp. 708 (N.D. Ill. 1994) (denying summary judgment where evidence adduced showed there was a possibility that defendants acted with the intention to defraud investors when issuing statements alleged to contain misrepresentations and omissions).

3. Loss Causation

In order to prove loss causation, a plaintiff must show that there is a "causal connection between the material misrepresentation and the loss." *Dura*, 544 U.S. at 341-42. In other words, the plaintiff must show at trial that "but for the circumstances that the fraud concealed, the investment would not have lost its value." *Caremark*, 113 F.3d at 648 (citations omitted) (internal quotation marks omitted). Where "fraud-on-the-market" is alleged, as it is here, plaintiffs must demonstrate "both that the defendants' alleged misrepresentations artificially

inflated the price of the stock and that the value of the stock declined once the market learned of the deception." *Ray* v. *Citigroup Global Mkts., Inc*., 482 F.3d 991, 995 (7th Cir. 2007). The misrepresentations or omissions alleged, however, "need not be the sole reason for the decline in value of securities, but it must be a 'substantial cause.'" *St. Clare* v. *Gilead Scis., Inc.*, 536 F.3d 1049, 1055-56 (9th Cir. 2008) (quoting *Robbins* v. *Koger Props., Inc*. 116 F.3d 1441, 1447 n.5 (11th Cir. 1997)).

Defendants do not dispute that there was a statistically significant decline in NeoPharm's stock on April 19, 2002. Rather, they contend that that decline was caused by the announcement that NeoPharm had commenced arbitration proceedings against Pharmacia because it jeopardized future collaborative drug development. Defs.' Mem. in Supp. at 11. Defendants maintain that the April 19 decline cannot be attributed to NeoPharm's misrepresentations or omissions because investors were aware prior to that date that there would be indefinite delays. As discussed above, however, the evidence does not show that, prior to April 19, 2002, investors were aware with the extent of the problems with LEP development. Accordingly, the court cannot conclude that, as a matter of law, the statistically significant stock decline immediately following NeoPharm's April 19 press release could not have resulted from the disclosure that significant problems with LEP development had led NeoPharm to take legal action against Pharmacia. As plaintiffs argue, investors may have first concluded on that date that LEP development would be indefinitely delayed, that LEP had likely lost its first mover advantage as a Taxol competitor and that LEP's commercial viability, and thus NeoPharm's value, was substantially reduced. This theory is supported by defendants' own admission that "an investigational drug's timeline to market is the information about which investors are most

concerned," Defs.' Reply at 5, as well as the Bloomberg report from the same day in which an analyst downgraded NeoPharm stock, explaining that the April 19 press release served as "clarification" on the LEP development timeline, an issue about which investors had been waiting to receive information since January. *See supra* at 24.

Defendants have moved to exclude the testimony of plaintiffs' loss causation expert, Bjorn L. Steinholt, on the basis that it is not reliable because (1) he assumes that defendants made misrepresentations when the evidence does not support this assumption; (2) the delay in LEP development was disclosed to the market on January 11, 2002 and therefore already incorporated into the stock price; and (3) he ignores the possibility that the April 19 drop was caused by the disclosure that NeoPharm had commenced arbitration against Pharmacia and that no new products would be licensed to Pharmacia pending the resolution of that dispute. The court declines to strike Steinholt's testimony on these bases because the court has already determined, without relying on his testimony, that there is an issue of fact as to whether defendants failed to disclose material information to investors, and as to whether, prior to April 19, 2002, the market was aware of the extent of problems with LEP such that investors knew LEP development had been indefinitely delayed. To the extent that defendants challenge Steinholt's method of analysis, defendants may raise this issue in a motion *in limine* prior to trial.

Because genuine issues of material fact exist as to all three disputed elements of plaintiffs' claims for statements made after January 14, 2002, summary judgment is inappropriate and defendants' motion will be denied.

II. Hussey's and Ahmed's Alleged Violations of Section 20(a)

Plaintiffs seek to hold Hussey and Ahmed liable under Section 20(a) of the Exchange

Act. Section 20(a) provides for the joint liability of control persons for securities violations. 15 U.S.C. § 78t(a). Such liability attaches if a defendant "exercised control over the operations of the person in general and . . . possessed the power or ability to control the specific transaction or activity upon which the primary violation was predicated, whether or not that power was exercised." *Harrison* v. *Dean Witter Reynolds, Inc.*, 974 F.2d 873, 881 (7th Cir. 1992). The parties do not dispute that Hussey and Ahmed were control persons within the meaning of Section 20(a). Accordingly, their liability is predicated upon whether there is an underlying violation of Section 10(b) and Rule 10b-5. Because there are genuine issues of material fact as to that issue for all statements made by NeoPharm after January 14, 2002, summary judgment is inappropriate on plaintiffs Section 20(a) claims in so much as they are based on those statements. To the extent plaintiffs' Section 20 (a) claims are predicated upon the October 31 press release, defendants' motion for summary judgment is granted.

CONCLUSION

For the reasons stated above, defendants' motion for summary judgment [165] is granted as to statements made before January 14, 2002 and denied as to all other statements. Defendants' motion to exclude the expert testimony of Bjorn I. Steinholt [162] is denied with leave to raise any challenges to his methodology in a motion in *limine* prior to trial.

Dated: March 31, 2010 ENTER:

JOAN HUMPHREY LEFKOW

United States District Judge