UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

RONALD KASSOVER, on his own behalf and on behalf of all those similarly situated,	:	NO. _____
Plaintiff,	:	CLASS ACTION
-against-	:	JURY TRIAL DEMANDED
OSI PHARMACEUTICALS, INC., COLIN GODDARD, ROBERT I. INGRAM, GABRIEL LEUNG, NICOLE ONETTO, ROBERT L. VAN NOSTRAND, MICHAEL ATIEH, G. MORGAN BROWNE, EDWIN A. GEE, DARYL K. GRANNER, WALTER M. LOVENBERG, VIREN MEHTA, HERBERT PINEDO, MARK RICHMOND, JOHN P. WHITE, MERRILL, LYNCH, PIERCE, FENNER & SMITH INCORPORATED, MORGAN STANLEY & CO. INCORPORATED, BANC OF AMERICA SECURITIES LLC, BEAR, STEARNS & CO. INC. AND LAZARD FRERES & CO. LLC,	:	
Defendants.	:	

CLASS ACTION COMPLAINT
FOR VIOLATIONS OF FEDERAL SECURITIES LAWS

This class action is brought by plaintiffs on behalf of purchasers of the common stock of OSIP Pharmaceuticals, Inc. ("OSIP" or the "Company") between October 26, 2004 and November 22, 2004, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act"). Plaintiffs allege that, based upon the investigation of plaintiffs' counsel, including without limitation: (a) review of United States Securities and Exchange Commission

("SEC") filings by OSIP; (b) review of regulatory filings and reports, including filings by OSIP with the Food and Drug Administration ("FDA"); (3) consultation with persons experienced in the FDA approval process for new drugs; (4) securities analysts' reports and advisories about the Company; (5) press releases and other public statements issued by the Company; and (6) media reports about the Company, the Company, the Individual Defendants and the Underwriter Defendants .caused, allowed and permitted a false and misleading registration statement and prospectus dated November 10, 2004 (the "November 2004 Registration Statement and Prospectus") to be issued, whereby $445,000,000 of OSIP stock was sold to the investing public at artificially inflated prices, which, when truth regarding OSIP's "flagship" drug, Tarceva, became known, caused the stock price to decline substantially, thereby causing millions of dollars of damages to plaintiff and the class.

NATURE OF THE ACTION

1. This action arises from OSIP's materially false and misleading statements and omissions to state facts that would make the statements not misleading concerning one of the Company's new anti-cancer drugs called Tarceva. Tarceva is represented by OSIP to be its "flagship" product. Tarecva is an anti-cancer drug that has been approved by the FDA on or about November 18, 2004 for use in treating lung cancer patients for whom initial chemotherapy treatments have not been helpful.

2. On or about November 4, 2004, OSIP issued a preliminary prospectus and registration statement on Form S-3/A in connection with its offering of 5,500,000 shares of OSIP common stock ("the November 4 Preliminary Prospectus and Registration Statement").

3. On or about November 10, 2004, OSIP issued a final prospectus on Form 424B4 offering 6,000,000 shares of OSIP common stock ("the November 10 Final Prospectus"). In the November 4 Preliminary Prospectus, OSIP represented to investors that Tarceva provided a meaningful survival benefit not just for patients who exhibit epidermal growth factor receptor ("EGFR") mutation, a mutation or "over-expression" that allows the cancer to keep growing. OSIP represented to the market that Tarceva also provided a meaningful survival benefit to patients whose tumors do not have an EGFR mutation. These claims were also made in the November 4 Preliminary Prospectus.

4. Thereafter, the underwriters of the offering exercised their over-allotment option, bringing the total offering to 6,900,000 shares of OSIP stock at $64.50 per share, for a total of over $445,000,000 (the "November 2004 Stock Offering").

5. These representations allowed OSIP to offer 6,900,000 shares of OSIP stock in the November offering and had a positive impact on OSIP's stock price, which reached as high as $67.45 per share during the Class Period.

6. Unfortunately for OSIP investors, however, these statements in the Prospectus and Registration Statement were materially false. OSIP attempted to minimize the impact on the Company's stock price of the fact that studies showed no survival benefit for EGFR-negative patients by stating OISP's BR.21 study results showed that the improvement in overall survival seen in the study could not be explained by the reported incidence of the EGFR mutations and that the study's results "demonstrate a meaningful, broad-based clinical benefit in a very advanced population of lung cancer patients."

7. What the defendants knew, but failed to disclose, was that the FDA thought that results of the study showing no survival benefit for EGFR-negative patients was important enough to require OSIP to indicate on Tarceva's labeling that studies did not show that Tarceva exhibited any survival benefit for non-EGFR patients. Defendants were aware of these results and the FDA's labeling requirement at least as early as October 26, 2004, the date OSIP committed to the FDA to perform postmarketing studies to determine the impact of Tarceva of the survival of both EGFR-positive and -negative patients. This fact was only disclosed on November 19, 2004, when a Piper Jaffray analyst stated theat there was a "Surprise" in the labeling that was finally approved by the FDA for Tarceva.

8. Whereas one would expect that the approval of Tarceva by the FDA would be met by the market with a bump up in OSIP's stock price, instead, in response to the disclosure in the Piper Jaffray analysis, OSIP's stock price dropped $6.09, or over 9%, in one day, from $64.25 on November 18, 2004 to $58.16 on November 19, 2004, on volume of 18,496,800 -- over ten times the previous day's volume -- and to $54.22 on the next trading day, November 22, 2004.

9. Defendants' materially false and misleading statements and omission of the truth about Tarceva allowed certain of them -- **in one day** -- to dump approximately 49,945 OSIP shares on an unsuspecting public and wrongly reap proceeds of over $2,830,007 at the expense of the investing public.

JURISDICTION AND VENUE

10. The federal securities claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act of 1934 (15 U.S.C. Sections 78j(b) and 78t(a), Rule 10b-5 promulgated

thereunder by the Securities and Exchange Commission (hereafter "SEC") [17 C.F.R. Section 240.10b-5], and Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 [15 C.F.R. Sections 77k, 77l and 77o]. The claims arising under Section 10(b) and Rule 10b-5 are based on fraud on the market.

11. This Court has jurisdiction over the subject matter of the federal securities claims pursuant to 28 U.S.C. Sections 1331 and 1337, Section 27 of the Exchange Act of 1934 [15 U.S.C. Section 78aa], and Section 22 of the Securities Act of 1933 [15 U.S.C. Section 77v].

12. Venue is proper in the Eastern District of New York pursuant to Section 27 of the Exchange Act of 1934, Section 22 of the Securities Act of 1933, 15 U.S.C. Section 77V, and 28 U.S.C. Section 1391(b). OSIP maintains its principal place of business at 58 South Service Road, Melville, New York 11747. Many of the acts and practices complained of herein occurred in substantial part in this district.

13. In connection with the acts and omissions alleged herein, Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

14. Plaintiff, as set forth in the certification annexed hereto, purchased common stock of OSIP at an artificially inflated prices during the Class Period and pursuant to the November 10 Final Prospectus and has been damaged thereby.

15. OSIP is a Delaware corporation with its principal place of business at 58 South

Service Road, Melville, New York 11747. OSIP focuses on the discovery, development, and commercialization of oncology products that attempt to both extend life and improve the quality-of-life for cancer patients around the world. OSI's targeted therapy agents focus on signal transduction inhibitors designed to block abnormal cell growth -- such as Tarceva -- or on compounds that seek to restore normal programmed cell death (apoptosis) in cancer cells. OSI also focuses on the development new and improved cytotoxic therapies. As set forth on OSIP's website, Tarceva is "our flagship product [and] was the first OSI drug to obtain FDA approval." As of July 31, 2004, the Company had 43,348,149 shares outstanding. Following the November 2004 Stock Offering, the Company had 49,086,747 shares outstanding.

16. Defendant Colin Goddard, Ph.D. ("Goddard") was, at all relevant times, Chief Executive Officer of OSIP. Defendant Goddard signed the November 4 Preliminary Prospectus and Registration Statement.

17. Defendant Robert A. Ingram ("Ingram") was, at all relevant times, Chairman of OSIP's Board of Directors. Defendant Ingram signed the November 4 Preliminary Prospectus and Registration Statement.

18. Defendant Gabriel Leung ("Leung") was, at all relevant times, Executive Vice President and President, Oncology Business of OSIP. On November 1, 2004, Leung sold 4,415 shares of OSIP stock at between $64.20 to $64.83 per share, reaping $285,000. Leung further exercised options at $23.85 per share, thereby reaping $88,245. Finally, Leung filed on November 1, 2004 to sell an additional 2,415 shares with an estimated value of $155,262. Thus, Leung advantage of his knowledge of material adverse information to reap approximately

$528,507 from his wrongful sale of OSIP shares.

19. Defendant Nicole Onetto ("Onetto") was, at all relevant times, Executive Vice President and Chief Medical Officer of OSIP. On November 1, 2004, Onetto sold 6,498 shares at $64.20 to $65.00 per share, exercising options at $21.55 to $45.01 per share, thereby wrongfully reaping proceeds of approximately $420,000.

20. Robert L. Van Nostrand ("Van Nostrand") was, at all relevant times, Vice President and Chief Financial Officer of OSIP. Van Nostrand signed the November 4 Preliminary Prospectus and Registration Statement. On November 1, 2004, Van Nostrand sold 2,750 shares at $64.20 to $64.83 per share, exercising options at $7.094 per share, thereby wrongfully reaping proceeds of approximately $177,000.

21. John P. White ("White") was, at all relevant times, a Director of OSIP who signed the November 4 Preliminary Prospectus and Registration Statement. On November 1, 2004, White sold 5,167 shares at $64.20 to $64.83 per share, exercising options at $9.25 per share, thereby wrongfully reaping proceeds of approximately $333,000.

22. Michael Atieh ("Atieh") was, at all relevant times, a Director of OSIP who signed the November 4 Preliminary Prospectus and Registration Statement.

23. G. Morgan Browne ("Browne") was, at all relevant times, a Director of OSIP who signed the November 4 Preliminary Prospectus and Registration Statement.

24. Edwin A. Gee ("Gee") was, at all relevant times, a Director of OSIP who signed the November 4 Preliminary Prospectus and Registration Statement.

25. Daryl K. Granner ("Granner") was, at all relevant times, a Director of OSIP who

signed the November 4 Preliminary Prospectus and Registration Statement.

26. Walter M. Lovenberg ("Lovenberg") was, at all relevant times, a Director of OSIP who signed the November 4 Preliminary Prospectus and Registration Statement.

27. Viren Mehta ("Mehta") was, at all relevant times, a Director of OSIP who signed the November 4 Preliminary Prospectus and Registration Statement.

28. Herbert Pinedo ("Pinedo") was, at all relevant times, a Director of OSIP who signed the November 4 Preliminary Prospectus and Registration Statement.

29. Mark Richmond ("Richmond") was, at all relevant times, a Director of OSIP who signed the November 4 Preliminary Prospectus and Registration Statement.

30. Defendants Goddard, Ingram, Van Nostrand, Atieh, Browne, Gee, Granner, Lovenberg, Mehta, Pinedo, Richmond and White are hereinafter referred to as the "Individual Defendants."

31. Defendants Goddard, Ingram, Leung, Onetto, Van Nostrand, Atieh, Browne, Gee, Granner, Lovenberg, Mehta, Pinedo, Richmond and White are hereinafter referred to as the "Individual Defendants."

32. Defendants Goddard, Ingram, Van Nostrand, Atieh, Browne, Gee, Granner, Lovenberg, Mehta, Pinedo, Richmond and White are hereinafter referred to as the "Individual Signatory Defendants."

33. Because of the Individual Defendants' positions with the Company, they had access to the adverse undisclosed information about its business, operations, products, operational trends, financial statements, markets and present and future business prospects via

access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and via reports and other information provided to them in connection therewith.

34. It is appropriate to treat the Individual Defendants as a group for pleading purposes and to presume that the false, misleading and incomplete information conveyed in the Company's public filings, press releases and other publications as alleged herein are the collective actions of the narrowly defined group of defendants identified above. Each of the above officers of OSIP, by virtue of their high-level positions with the Company, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, products, growth, financial statements, and financial condition, as alleged herein. Said defendants were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

35. As officers and controlling persons of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and was traded on the NASDAQ National Market (the "NASDAQ"), and governed by the provisions of the federal

securities laws, the Individual Defendants each had a duty to disseminate promptly, accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

36. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public and shareholder and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature. Because of their Board membership and/or executive and managerial positions with OSIP, each of the Individual Defendants had access to the adverse undisclosed information about OSIP's business prospects and financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about OSIP and its business issued or adopted by the Company materially false and misleading.

37. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged

herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each of the Individual Defendants is responsible for the accuracy of the public reports and releases detailed herein and is therefore primarily liable for the representations contained therein.

38. As set forth above, **in one day** defendants Goddard, Leung, Onetto, Van Nostrand and White dumped approximately 49,945 OSIP shares on an unsuspecting public and wrongly reaped proceeds of over $2,830,007 at the expense of the investing public.

39. Defendant Merrill, Lynch, Pierce, Fenner & Smith Incorporated ("Merrill Lynch") is an investment banking firm with its headquarters located at 4 World Financial Center, 250 Vesey Street, New York, New York. Merrill Lynch acted as a co-lead underwriter of the November 2004 Stock Offering. In connection with this offering, Merrill Lynch shared in the underwriting discount and fees of approximately $24,277,000.

40. Defendant Morgan Stanley & Co., Incorporated ("Morgan Stanley") is an investment banking and brokerage firm headquarters at 1585 Broadway, New York, NY 10036. Morgan Stanley acted as a co-lead underwriter of the November 2004 Stock Offering. In connection with this offering, Morgan Stanley shared in the underwriting discount and fees of approximately $24,277,000.

41. Defendant Banc of America Securities LLC, ("BOAS") a subsidiary of Bank of America Corporation, is an investment banking and brokerage firm headquarters at 9 West 57th Street, New York, New York. BOAS acted as a co-lead underwriter of the November 2004 Stock Offering. In connection with this offering, BOAS shared in the underwriting discount and

fees of approximately $24,277,000.

42. Defendant Bear Stearns & Co., Inc. ("Bear Stearns") is an investment banking and brokerage firm headquarters at 383 Madison Ave, New York, NY 10179. Bear Stearns acted as a co-lead underwriter of the November 2004 Stock Offering. In connection with this offering, Bear Stearns shared in the underwriting discount and fees of approximately $24,277,000.

43. Defendant Lazard Freres & Co. LLC. ("Lazard") is an investment banking and brokerage firm headquarters at 30 Rockefeller Plaza, New York, NY 10020. Lazard acted as a co-lead underwriter of the November 2004 Stock Offering. In connection with this offering, Lazard shared in the underwriting discount and fees of approximately $24,277,000.

44. Each of the defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of OSIP common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding OSIP's business, operations, management and the intrinsic value of OSIP common stock; (ii) deceived the investing public in connection with the benefits provided by Tarceva to EGFR-negative patients; and (iii) caused plaintiffs and other members of the Class to purchase OSIP securities at artificially inflated prices.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

45. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased the common stock of OSIP either (a) pursuant to OSIP's offering of 6,000,000 common shares of

OSIP stock at $64.50 per share on or about November 10, 2004 and/or (b) on the open market between October 26, 2004 and November 19, 2004, inclusive (the "Class Period") and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

46. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, OSIP common shares were actively traded on the NASDAQ. While the exact number of Class members is unknown to plaintiffs at this time and can only be ascertained through appropriate discovery, plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by OSIP or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of July 31, 2004, the Company had 43,348,149 shares outstanding.

47. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

48. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

49. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the

questions of law and fact common to the Class are:

(a) Whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) Whether defendants participated in and pursued the common course of conduct complained of herein;

(c) Whether documents filed with the SEC and other documents, press releases and statements disseminated to the investing public and OSIP's shareholders during the Class Period misrepresented material facts about the utility of Tarceva for EGFR-negative patients;

(d) Whether the market price of OSIP's common stock during the Class Period was artificially inflated due to the material misrepresentations and failure to correct the material misrepresentations complained of herein; and

(e) To what extent the members of the Class have sustained damages and the proper measure of damages.

50. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

False and Misleading Statements in OSIP's November 2004 Secondary Offering

51. As set forth above, on or about November 4, 2004, OSIP issued the November 4 Preliminary Prospectus in connection with its offering of 5,500,000 shares of OSIP common stock.

52. On or about November 10, 2004, OSIP issued the November 10 Final Prospectus, which set forth the results regarding Tarceva's results claiming that Tarceva provided a meaningful survival benefit to patients who were EGFR-negative. The offering price of the 6,000,000 shares of OSIP common stock was $64.50 per share, thereby raising approximately $445,000,000.

53. The November 10 Final Prospectus specifically represented that, although some studies indicated that EGFR-inhibitors such as Tarceva had a benefit only for patients who were EGFR-positive, Tarceva provided a meaningful survival benefit not just for patients who exhibit the EGFR mutation. OSIP represented to the market that Tarceva also provided a meaningful survival benefit to patients whose tumors do not have an EGFR mutation:

> Recent publications have shown a strong correlation of tumor response with a group of newly-identified EGFR mutations in lung cancer which are clustered in patients who are non-smokers or have tumors with adenocarcinoma histology. These publications claim that the clinical benefit observed for EGFR inhibitors in NSCLC may be restricted to patients whose tumors have these EGFR mutations. The BR.21 study results clearly show, however, that tumor response is not always a good surrogate for survival benefit and that the improvement in overall survival seen in our BR.21 study cannot be explained by the reported incidence (approximately 10%) of these mutations. A survival benefit was seen in our pancreatic cancer study despite the fact that there was no difference in tumor response rates between the two arms in the

> study and that publications in scientific literature indicate that the mutations may be largely confined to lung cancer. This supports our belief that a much broader group of patients than those achieving a tumor response derive a meaningful survival benefit from treatment with Tarceva(TM).
>
> We believe our BR.21 results are particularly noteworthy in that they demonstrate a meaningful, broad-based clinical benefit in a very advanced population of lung cancer patients. The cytotoxic chemotherapy agents, Taxotere(R) and Alimta(R), showed similar survival results in a recent Phase III study comparing the two drugs; however, these agents exhibited a severe side-effect profile and were tested in a less advanced patient population. In contrast, Tarceva(TM) has a relatively benign side-effect profile and the BR.21 study enrolled second and third-line patients, many of whom were in poorer overall health.

(Emphasis supplied).

54. The November 10 Final Prospectus represented further that Tarceva would be useful in treating EGFR-negative patients as follows:

> Data suggests that patients with lung tumors possessing these [EGFR] mutations may constitute the majority of patients seen to have a tumor response when treated with these [EGFR inhibiting] agents and some investigators have hypothesized that the clinical benefits observed for EGFR inhibitors may be restricted to patients whose tumors have these EGFR mutations. However, our BR.21 study clearly shows that tumor response is not always a good surrogate for survival benefit and that the improvement in overall survival cannot be explained by the reported incidence (approximately 10%) of these mutations.

(Emphasis supplied).

55. These statements in the November 2004 Prospectus and Registration Statement were materially false and misleading and omitted to state facts that would make them not misleading in that, as set forth below, the defendants knew, at least as early as October 26, 2004,

that (1) the FDA would require that OSIP disclose in its labeling for Tarceva that no survival benefit was observed in the EGFR-negative subgroup as part of the BR.21 study; and (2) OSIP did not have sufficient data to claim that Tarceva provided a survivability benefit for EGFR-negative patients.

56. On November 10, 2004, OSIP's common stock price closed at $65.50 per share.

57. On or about November 17, 2004, OSIP announced the completion of its previously announced public offering of 6,000,000 shares of its common stock and completion of the additional sale of 900,000 shares of common stock pursuant to the full exercise by the underwriters of their over-allotment option.

58. On November 17, 2004, OSIP closed at $65.45 per share.

FDA Approval of Tarceva

59. On November 18, 2004, the FDA notified OSIP that it had approved Tarceva for marketing.

60. The FDA Approval Letter reminded OSIP that the Company had committed, on October 26, 2004 and November 16, 2004, to six postmarketing studies. Significantly, two of the studies were to detect progression free survival and overall survival for a subgroup that was EGFR-positive and a subgroup that was EGFR-negative:

> We remind you of your postmarketing study commitments in your submission dated October 26, 2004 and November 16, 2004. Thee commitments are listed below.
>
> 1. STUDY DESCRIPTION: A double-blind randomized Phase 3 study to evaluate te efficacy of Traceva or placebo following 4 cycles of platinum-based chemotherapy in patients with histologically documented advance or

recurrent (stage IIIB and not amenable for combined modality treatment) or metastatic (Stage IV) non-small cell lung cancer (NSCLC) who have not experience disease progression or unacceptable toxicity during chemotherapy. The primary experienced disease progression or unacceptable toxicity during chemotherapy. The primary endpoint will be PFS [progression free survival]. The study will also be sized to detect a realistic difference in survival. For eligibility all patients must have EGFR expression status determined by Dako Kit prior to randomization. Analyses of results will include assessment of treatment effect in the subgroup with EGFR expression status positive and the subgroup with EGFR expression status negative.

Protocol submission date: March, 2005
Study Start: June, 2005
Final Report Submission December, 2008

2. STUDY DESCRIPTION: A randomized Phase 3 study to evaluate the efficacy of Tarceva or chemotherapy (Alimta or Taxotere) following 4 cycles of platinum-based chemotherapy in patients with histologically documented advanced or recurrent (stage IIIB and not amenable for combined modality treatment) or metastatic (Stage IV) non-small cell lung cancer (NSCLC) who have experienced disease progression or unacceptable toxicity during chemotherapy. The primary endpoint will be overall survival (subject to FDA agreement during SPA review). For eligibility all patients must have EGFR expression status determined by Dako Kit prior to randomization. Analyses of results will include assessment of treatment effect in the subgroup with EGFR expression status positive and the subgroup with EGFR expression status negative.

Protocol submission date: March, 2005
Study Start: June, 2005
Final Report Submission December, 2008

(Emphasis supplied).

61. Thus, at least as early as October 26, 2004, when OSIP's stock price closed at $62.67 per share, defendants knew that they had no definitive finding as to Tarceva's efficacy for patients who were EGFR-negative, and in fact were required by the FDA to conduct further

studies to specifically determine the survival benefit for that subgroup.

62. That same day, November 18, 2004, OSIP announced the FDA's approval of Tarceva for marketing:

FDA Approves Tarceva-TM- For Patients with Advanced Non-Small Cell Lung Cancer; Only Targeted EGFR Therapy Shown to Improve Survival in Advanced Non-Small Cell Lung Cancer

MELVILLE, N.Y. & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 18, 2004--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) and Genentech, Inc. (NYSE: DNA) announced today that the U.S. Food and Drug Administration (FDA) has approved, after priority review, Tarceva(TM) (erlotinib) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. Tarceva(TM) is an oral tablet indicated for daily administration. Tarceva(TM) is the only drug in the epidermal growth factor receptor (EGFR) class to demonstrate in a Phase III clinical trial an increase in survival in advanced NSCLC patients. Tarceva(TM) will be available within five shipping days.

"The FDA approval of erlotinib marks an important new treatment option for patients in the United States with advanced non-small cell lung cancer after chemotherapy has failed," said Alan Sandler, M.D., associate professor of medicine at Vanderbilt University and medical director of the Thoracic Oncology Department. "Physicians will now be able to offer patients a new therapy that has been proven to increase survival and that is different from traditional cytotoxic chemotherapy treatment."

The FDA based its approval decision for Tarceva(TM) on results from a randomized double-blind, placebo-controlled pivotal Phase III trial of patients with second and third-line advanced NSCLC. In this pivotal study, patients receiving Tarceva(TM) had a median survival of 6.7 months compared to 4.7 months in patients who received placebo (a 42.5 percent improvement). A hazard ratio (HR) of 0.73 and a p-value of less than 0.001 were determined for comparisons of overall survival (HR of less than one indicates a reduction in the risk of death and a p-value of less than 0.05 indicates statistical significance). In addition, 31.2 percent of patients receiving Tarceva(TM) in the study were alive at one year versus 21.5 percent in the placebo arm.

Results from two earlier large, randomized, placebo-controlled clinical trials in first-line advanced NSCLC patients showed no clinical benefit with concurrent administration of Tarceva(TM) with doublet platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

In the pivotal trial, the most common adverse reactions in patients receiving Tarceva(TM) were rash and diarrhea. Grade three/four rash and diarrhea occurred in nine and six percent of Tarceva(TM)-treated patients, respectively. Rash and diarrhea each resulted in discontinuation of one percent of Tarceva(TM)-treated patients. Six and one percent of patients needed dose reduction for rash and diarrhea, respectively.

> Historically, there have been infrequent reports of serious interstitial lung disease (ILD), including fatalities, in patients receiving Tarceva(TM) for treatment of NSCLC or other advanced solid tumors. In the Phase III trial, severe pulmonary reactions, including potential cases of interstitial lung disease, were infrequent (0.8 percent) and were equally distributed between treatment arms. The overall incidence of ILD in Tarceva(TM)-treated patients from all studies was approximately 0.6 percent.
>
> "This is a significant day for non-small cell lung cancer patients and their families," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "Tarceva(TM) offers a new kind of therapy for advanced lung cancer patients, not only providing improved survival, but doing so without many of the side effects associated with conventional chemotherapy."
>
> "The FDA approval of Tarceva(TM) is the result of extraordinary effort and commitment by many employees at OSI and Genentech, clinical investigators, the FDA, and most importantly, the patients who volunteered to be part of the clinical trial that resulted in this approval," said Arthur D. Levinson, Ph.D., Genentech's chairman and chief executive officer.

63. Defendants, in the November 18, 2004 press release, failed to disclose (a) that the FDA was requiring OSIP to change the labeling for Tarceva to include study results that indicated no survival benefit for EGFR-negative patients; and (b) that there was no proven benefit for EGFR-negative patients, critical omissions given the size of the target populations for Tarceva and the possibility that doctors would choose not to prescribe a regimen of Tarceva for EGFR-negative patients.

64. On November 18, 2004, OSIP's stock price closed at $64.25 per share.

The Truth Is Disclosed

65. Far from OSIP's stock price increasing or remaining level following the announcement of the approval of Tarceva, OSIP's stock price dropped to $58.16 per share on November 19, 2004 on volume of 18,496,800 -- over ten times the previous day's volume.

66. The reason for this extraordinary decline was a Piper Jaffray analyst report

authored by Thomas Weis, a senior research analyst. In his November 19, 2004 analyst report, Mr. Weis commented on the FDA's approval of Tarceva and a "surprise" in the labeling of Tarceva:

> **Surprise in the Tarceva Label: EGFR Testing?**
> **KEY POINTS:**
> - Tarceva Approved By FDA. The FDA approved Tarceva yesterday for the treatment of locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy. This approval was in advance of its January action date, not surprising given the survival benefit shown in the Phase III BR.21 data and submitted to the agency.
>
> - *Surprise in the Label*: Subgroup Analysis of EGFR Expression Data. The package insert for Tarceva was generally in line with our expectations, except for a prominent section entitled "Relation of Results to EGFR Protein Expression Status (as Determined by Immunohistochemistry.)." In this section, the label describes subgroups analyzed by EGFR status tested using the DAKO EGFR pharmDx kit. As reminder, EGFR is the target enzyme to Tarceva. The analysis compares the survival of EGFR-positive patients (n127), EGFG-negative patients (n=111) and EGFR- unmeasured patients (n = 493). *The analysis suggests that a survival benefit was observed in the EGFR-positive* (hazard ratio, HR = 0.65) and EGFR - unmeasured (HR = 0.76) *subgroups but not in the EGDFR-negative subgroup* (HR = 1.01). The label does state that the confidence intervals overlap, and thus, a survival benefit in the EGFR-negative subgroup cannot be ruled out. As a result, there is not recommendation for EGFR testing. *However, we note that his subgroup analysis was not presented as part of the original BR.21 data at ASCO and its inclusion in the label suggests that the FDA found the analysis important for physicians to consider. If physicians choose to limit their usage to EGFR-positive patients, our estimates for sales in lung cancer, which assume 555 penetration of the relapsed market at peak, may prove aggressive.*

(Emphasis supplied).

67. This was the first time these results were disclosed – amazingly, these results were not disclosed by OSIP at the American Society of Clinical Oncology held in June, 2004, where

OSIP presented the results of its testing of Tarceva.

68. The market reacted swiftly and harshly to the disclosure of Tarceva's limitations. Following the publication of this report, OSIP's stock price dropped from $58.16 per share on Friday, November 19, 2004 to $54.22 per share on Monday, November 22, 2004.

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69. Defendants' actual knowledge of the true adverse information concerning Tarceva is reflected in:

(a) OSIP's October 26, 2004 submission to the FDA in connection with Tarceva's NDA, as set forth above;

(b) Tarceva's status as OSIP's "flagship" product, as set forth above;

(c) the fact that OSIP made 32 different submissions to the FDA regarding Tarceva prior to the November 10, 2004 stock offering; and

(d) insider sales by defendants Goddard, Leung and Onetto on November 1, 2004 of approximately 49,945 OSIP shares of common stock thereby reaping proceeds of over $2,830,007 **in one day**, as set forth above.

No Safe Harbor

70. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no

meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for purportedly those false forward-looking statements because at the time each of those purportedly forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of OSIP who knew that those statements were false when made.

The Liability of the Underwriter Defendants.

71. In connection with the registration process of the stock offered in the November 2004 Stock Offering, the Underwriter Defendants were obligated to perform reasonable investigation into the Company's business and operations and ensure that the statements in the November 2004 Registration and Prospectus were not materially false and misleading. In the process of conducting their "due diligence" investigation, the Underwriter Defendants should have exercised a high degree of care and sought to independently verify the Company's representations.

72. As set above, the results of OSIP's BR.21 study clearly showed that Tarceva provided no survival benefit for EGFR-negative patients -- indeed, this was plain enough to the FDA to require its disclosure in Tarceva's labeling. The Underwriter Defendants failed to perform a reasonable investigation in connection with their duty to understand the results of the BR.21 study and the FDA's labeling requirement. Had the Underwriter Defendants performed

customary investigation into Tarceva's performance, they would have discovered the results of the study and the FDA's labeling requirement and they would have discovered the material misrepresentations and the material omissions in the November 2004 Registration Statement and Prospectus.

COUNT I

(Against Defendants OSIP, the Individual Signatory Defendants and the Underwriter Defendants For Violation of Section 11 of the Securities Act)

73. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein, except such paragraphs must, for purposes of this Count, be read to wholly exclude a claim or element of fraud.

74. This Count is brought against defendants OSIP, Goddard, Leung and the Underwriter Defendants pursuant to Section 11 of the Securities Act, 15 U.S.C. Section 77k, on behalf of all purchasers of OSIP common stock pursuant to the November 2004 Stock Offering.

75. The November 2004 Stock Offering Registration Statement and Prospectus, which became effective on or about November 10, 2004, was materially false and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements therein not misleading, and failed to adequately disclose material facts as set forth above.

76. Purchasers of OSIP stock pursuant to the November 2004 Registration Statement and Prospectus purchased or otherwise acquired OSIP common stock in or traceable to the November 2004 Stock Offering and issued pursuant to the November 2004 Registration

Statement and Prospectus.

77. Purchasers of OSIP stock pursuant to the November 2004 Registration Statement and Prospectus did not know of the material omissions or false and misleading statements when they purchased the OSIP common stock.

78. By reason of the foregoing, pursuant to Section 11 of the Securities Act, defendants OSIP, Goddard, Ingram and the Underwriter Defendants are liable to purchasers of OSIP stock pursuant to the November 2004 Registration Statement and Prospectus for damages as provided by the Securities Act.

79. This action is being brought within one year after the discovery of the untrue statements and omissions and within three years after OSIP common stock was issued to the public pursuant to the November 2004 Stock Offering.

COUNT II

(Against Defendants OSIP and the Individual Signatory Defendants For Violation of Section 15 of the Securities Act)

80. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein, except such paragraphs must, for purposes of this Count, be read to wholly exclude a claim or element of fraud.

81. This Count is brought pursuant to Section 15 of the Securities Act, 15 U.S.C. Section 77o, on behalf of all purchasers of OSIP common stock pursuant to the November 2004 Stock Offering against defendants Goddard and Ingram .

82. Defendants Goddard and Ingram acted as controlling persons of OSIP within the

meaning of Section 15 of the Securities Act. By virtue of their high-level positions at OSIP, participation in and/or awareness of OSIP's operations and/or intimate knowledge of OSIP's products, and the actual progress of its development of Tarceva, defendants Goddard and Ingram had the power to influence and control and did influence and control, directly or indirectly, the decision-making of OSIP as well as the day-to-day activities thereof, including the content and dissemination of the November 2004 Prospectus and Registration Statement which the plaintiff herein alleges herein is false and misleading.

83. Pursuant to Section 15 of the Securities Act, by virtue of their positions as controlling persons of OSIP, defendants Goddard and Ingram are liable, jointly and severally, with and to the same extent as OSIP for OSIP's aforesaid violations of Section 15 of the Securities Act as alleged herein.

84. Plaintiff and purchasers of OSIP common stock pursuant to the November 2004 Stock Offering are entitled to damages as provided by the Securities Act.

COUNT III

(Against the Underwriter Defendants
For Violation of Section 12(a)(2) of the Securities Act)

85. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein, except such paragraphs must, for purposes of this Count, be read to wholly exclude a claim or element of fraud.

86. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 771, on behalf of the purchasers of OSIP stock pursuant or traceable to the November

2004 Stock Offering against the Underwriter Defendants.

87. The November Registration Statement and Prospectus was materially false and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements therein not misleading, and failed to adequately disclose material facts as set forth above.

88. The Underwriter Defendants' actions of solicitation include participating in the preparation of the November 2004 Stock Offering's false and misleading Registration Statement and Prospectus.

89. Purchasers of OSIP common stock pursuant or traceable to the November 2004 Registration Statement and Prospectus did not know of any of the untruthful statements and omissions alleged herein, and in the exercise of reasonable care could not have known them.

90. This action has been filed within three years of the public offering and within one year of the time the purchasers of OSIP common stock pursuant or traceable to the November 2004 Registration Statement and Prospectus discovered or reasonably could have discovered the existence of the untrue statements by exercising due diligence.

91. Purchasers of OSIP common stock pursuant or traceable to the November 2004 Registration Statement and Prospectus are entitled to damages caused by the Underwriter Defendants' violations of Section 12(a)(2) of the Securities Act, as provided therein.

COUNT IV

**(Against All Defendants For
Violation of Section 10(b) of the Exchange Act and
Rule 10b-5 of the Securities and Exchange Commission)**

92. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

93. This Count is asserted against all defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder.

94. During the Class Period, defendants, singularly and in concert, directly engaged in a common plan, scheme, and unlawful course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business which operated as a fraud and deceit upon plaintiffs and the other members of the Class, and made various deceptive and untrue statements of material facts and omitted to state material in order to make the statements made, in light of the circumstances under which they were made, not misleading to plaintiffs and the other members of the Class. The purpose and effect of said scheme, plan, and unlawful course of conduct was, among other things, to induce plaintiffs and the other members of the Class to purchase OSIP common stock during the Class Period at artificially inflated prices.

95. During the Class Period, defendants, pursuant to said scheme, plan, and unlawful course of conduct, knowingly and/or recklessly issued, caused to be issued, participated in the issuance of, the preparation and issuance of deceptive and materially false and misleading

statements to the investing public as particularized above.

96. Throughout the Class Period, OSIP acted through the Individual Defendants, whom it portrayed and represented to the financial press and public as its valid representative. The knowledge and/or recklessness of the Individual Defendants are therefore imputed to OSIP, which is primarily liable for the securities law violations while acting in their official capacities as Company representatives, or, in the alternative, which is liable for the acts of the Individual Defendants under the doctrine of respondent superior.

97. As a result of the dissemination of the false and misleading statements set forth above, the market price of OSIP common stock was artificially inflated during the Class Period. In ignorance of the false and misleading nature of the statements described above and the deceptive and manipulative devices and contrivances employed by said defendants, plaintiffs and the other members of the Class relied, to their detriment, on the integrity of the market price of the stock in purchasing OSIP common stock. Had plaintiffs and the other members of the Class known the truth, they would not have purchased said shares or would not have purchased them at the inflated prices that were paid.

98. Plaintiffs and the other members of the Class have suffered substantial damages as a result of the wrongs herein alleged in an amount to be proved at trial.

99. By reason of the foregoing, defendants directly violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts in order to make the statements made, in light of the circumstances under which

they were made, not misleading; or (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon plaintiffs and the other members of the Class in connection with his purchases of OSIP common stock during the Class Period.

COUNT V

(Against The Individual Defendants For Violation of Section 20(a) of the Exchange Act)

100. Plaintiffs repeat and reallege each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

101. The Individual Defendants, by virtue of their positions, stock ownership and/or specific acts described above, were, at the time of the wrongs alleged herein, controlling persons within the meaning of Section 20(a) of the Exchange Act.

102. The Individual Defendants had the power and influence and exercised the same to cause OSIP to engage in the illegal conduct and practices complained of herein.

103. By reason of the conduct alleged in prior Count of the Complaint, the Individual Defendants are liable for the aforesaid wrongful conduct, and are liable to plaintiffs and to the other members of the Class for the substantial damages which they suffered in connection with his purchases of OSIP common stock during the Class Period.

WHEREFORE, plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of plaintiff and the other Class

members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: December 16, 2004

SCHOENGOLD SPORN LAITMAN & LOMETTI, P.C.

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