AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS
INTRODUCTION AND SUMMARY

1. Lead Plaintiff, State Universities Retirement System, brings this action on behalf of itself and all persons who purchased or otherwise acquired the publicly traded securities of AstraZeneca PLC (“AstraZeneca” or the “Company”) between April 2, 2003 and September 10, 2004, inclusive (the “Class Period”), for violations of §§10(b), 20(a) and 20A of the Securities Exchange Act of 1934 (“Exchange Act”). AstraZeneca is an international pharmaceutical research and development company whose securities trade on the New York Stock Exchange (“NYSE”), the London Stock Exchange and the Stockholm Stock Exchange.

2. As alleged herein, during the Class Period, defendants made a series of material misrepresentations about Exanta, an anticoagulation drug AstraZeneca was developing for regulatory approval to market in the U.S. and abroad. Exanta was one of AstraZeneca’s three most important new drugs in the Company’s drug development pipeline, as it was in the final stages of development and would be submitted to regulatory authorities in the United States and Europe for marketing approval in 2003. The approval and launch of Exanta was also critical to boost AstraZeneca’s revenues, which had been declining drastically due to the expiration of patents on several of its highest revenue-generating drugs. If approved, Exanta was projected to have worldwide sales of $1.5 to $3 billion.

3. Defendants told investors throughout the Class Period that Exanta was at least as effective as the gold standard oral anticoagulant, warfarin, and was in fact preferable to warfarin due to many demonstrated advantages over that drug; Exanta was safe for long and short-term use, and had a compelling risk-benefit profile because the risks of any serious adverse events from taking the drug outweighed the benefits it provided in meeting a widespread medical need; Exanta reduced the risk of heart attack in high-risk patients; and while Exanta caused increased liver enzymes in some patients, a potential predictor of liver injury, the elevations were mild, transient, reversible and...
resolved spontaneously whether Exanta was continued or discontinued, and thus did not upset the drug’s risk-benefit profile, particularly because they could be safely monitored. Investors were thus led to believe that Exanta was likely to be approved for marketing and would dominate the global oral anticoagulant market. As a result of defendants’ false and misleading statements about Exanta, the Company’s securities traded at inflated levels on the New York, London and Stockholm Stock Exchanges throughout the Class Period, reaching Class Period highs of $51.20 per share on the NYSE, £28.94 per share on the London Stock Exchange, and 380.50 SEK per share on the Stockholm Stock Exchange.

4. Defendants submitted a New Drug Application (“NDA”) for marketing approval of Exanta in the United States to the U.S. Food & Drug Administration (“FDA”) in December 2003. The NDA included all data from clinical trials of Exanta, and was not available to the public. On September 9, 2004, FDA investigators posted several reports on the Exanta clinical trials on the FDA website, in anticipation of a September 10, 2004 meeting of the FDA’s Cardiovascular and Renal Advisory Committee (“Advisory Committee”) to consider approval of Exanta. The FDA reports revealed for the first time troubling facts about the results of the clinical trials of Exanta which contradicted what defendants had been telling investors since April 2003. In summary, the FDA reports disclosed that:

(a) Exanta presented a serious risk of drug-induced severe or fatal liver injury, which could not be adequately minimized with monitoring due to the unpredictable nature of the enzyme elevations caused by the drug. In fact, nine patients treated with Exanta in the trials had died with severe liver injury. Furthermore, long-term use of Exanta, if approved, would require stringent liver function monitoring on a monthly or weekly basis, depending on the degree of liver enzyme elevations;
(b) Exanta posed a substantial risk of coronary artery disease events including heart attack, which was particularly troubling since defendants sought to market the drug to heart attack survivors; and

(c) The clinical trials of Exanta did not establish that it was as effective as warfarin or that it was a preferable treatment to warfarin.

5. These revelations posed a serious question about Exanta’s risk-benefit profile, whether Exanta would be approved by the FDA and what the market potential for the drug would be if approved. As a result of the FDA’s reports on September 9, 2004, AstraZeneca’s stock and prices declined precipitously on all three exchanges on very high trading volumes from September 8 to September 9, falling from $47.05 to $44.40 on volume of 12,673,100 shares on the NYSE; from £26.19 to £25.10 on volume of 32,852,316 in London; and from 352.50 SEK to 337.00 SEK on volume of 3,755,415 in Stockholm. Prices fell further on September 10 to $43.74 on the NYSE, £24.50 in London and to 334.50 SEK in Stockholm. However, the FDA investigator reports did not represent the FDA’s official opinion about Exanta, and the data in them would be analyzed and evaluated by the Advisory Committee before the FDA would decide on approval. Consequently, the data in the reports constituted only a partial disclosure and the prices of AstraZeneca’s securities remained artificially inflated following these disclosures.

6. At the Friday, September 10, 2004 Advisory Committee meeting, both AstraZeneca representatives and FDA representatives presented their views on Exanta’s safety and efficacy based on data from the clinical trials. After a full day of presentations and discussion, the Advisory Committee voted 11 to 1 against approval of Exanta because of the safety and efficacy concerns raised in the FDA reports. Defendants announced the Advisory Committee’s recommendation after the market closed that day.
7. As a direct result of the news about the September 10 meeting and the Advisory Committee’s recommendation, AstraZeneca’s securities continued to fall on Monday, September 13 to $41.80 on the NYSE, £23.40 in London and 312.00 SEK in Stockholm. Thus, in response to the September 9 and 10, 2004 news, AstraZeneca’s stock and American Depository Receipt (“ADR”) prices declined precipitously on all three exchanges on very high trading volumes from September 8 through September 13, falling from $47.05 to $41.80, 11.1%, on the NYSE; from 352.50 SEK to 312 SEK, 11.49%, in Stockholm; and from £26.19 to £23.40, 10.6%, in London.

8. Throughout the Class Period, defendants knew but concealed all of the facts disclosed by the FDA in its September 9 reports and that as a result, Exanta’s risk-benefit and safety profiles were poor, the FDA was unlikely to approve Exanta for long-term or even short-term use and defendants’ revenue projections for Exanta were false and misleading. Defendants had access to all data related to the clinical trials, the protocols for the Exanta studies, and the NDA and all communications related to it. Prior to and throughout the Class Period, AstraZeneca met with the FDA to discuss the very safety and efficacy data that shocked investors when disclosed on September 9 and 10, 2004.

9. Defendants also benefited from their knowledge of undisclosed material data. While prices of AstraZeneca’s securities were artificially inflated due to defendants’ misrepresentations, the officers and directors named herein as defendants collectively disposed of 62,139 shares of AstraZeneca stock for proceeds of about $3.27 million in U.S. dollars. The artificially high price of AstraZeneca stock also enabled defendants to complete a secondary placement of 21.2 million shares in Sweden in February 2004 at 352 SEK per share, for proceeds amounting to over $1 billion in U.S. dollars.
10. The following chart illustrates the inflation of AstraZeneca’s securities on all three exchanges and key events during the Class Period, and its decline upon the FDA’s revelations:

11. On October 11, 2004, the FDA issued its action letter rejecting Exanta, and in February 2006, AstraZeneca announced that it was withdrawing Exanta, which had been approved in Europe for short-term use, from the global market because of the risk of severe liver injury, and was discontinuing further development of the drug.

JURISDICTION AND VENUE

12. The claims asserted arise under and pursuant to §§10(b), 20(a) and 20A of the Exchange Act and Rule 10b-5 promulgated thereunder. Jurisdiction is conferred by §27 of the Exchange Act. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act.
13. This Court has subject matter jurisdiction over the claims brought on behalf of investors who purchased or acquired AstraZeneca securities on foreign markets and/or on the NYSE because:

   (a) Defendants’ wrongful conduct alleged herein had a substantial effect upon the U.S. markets, U.S. investors, and the prices of ADRs and ordinary shares registered in the U.S. and listed on U.S. security exchanges.

   (b) Defendants’ activities in the United States were more than merely preparatory to a securities fraud conducted elsewhere and their activities or culpable failures to act within the United States directly caused plaintiffs’ losses.

   (c) AstraZeneca maintains many offices and facilities throughout the U.S. which are a critical and dominant component of the Company’s global business. AstraZeneca’s U.S. offices are located in California (Woodland Hills and Torrance); Delaware (Newark and Wilmington); District of Columbia; Florida (Coral Gables and Tampa); Illinois (Schaumburg); Massachusetts (Boston, Waltham and Westborough); Michigan (Detroit); Pennsylvania (Wayne); Puerto Rico (Hato Rey); Tennessee (Franklin); and Texas (Irving).

   (d) On a global basis, AstraZeneca collected its greatest amount of revenue during the Class Period from its U.S. operations: $9.6 billion in 2004 and $8.7 billion in 2003. The Company’s U.S. sales accounted for approximately 46% of its global sales of $21.4 billion in 2003, and for 45% of its global sales of $18.8 billion in 2004. AstraZeneca lists its official accounting currency as dollars.

   (e) Currently, AstraZeneca is the fifth largest pharmaceutical company in the U.S. Almost 14,000, or 21%, of AstraZeneca’s 65,000 employees are located in the U.S.
(f) AstraZeneca’s ADRs are listed and traded on the NYSE and the Company files regular, periodic reports with and is subject to the jurisdiction of the SEC and thus the U.S. federal securities laws. As of December 2004, AstraZeneca had outstanding approximately 45,000 holders of ADRs, which are issued by JPMorgan Chase Bank.

(g) Defendants utilized the U.S. mails, interstate wires and the facilities of the U.S. securities exchange in furtherance of the fraud alleged herein. Among other things, AstraZeneca conducted numerous conference calls with analysts located in the U.S., distributed its materially misleading reports to shareholders residing throughout the U.S., prepared many of its misleading press releases in its Wilmington, Delaware office and distributed those press releases from there.

(h) As alleged herein, all defendants conducted meetings with analysts and investors throughout the U.S. during the Class Period, and AstraZeneca’s Annual Business Review was held in Wilmington, Delaware in October 2003.

(i) Defendants have engaged in extensive contact with U.S. regulatory agencies, such as the FDA and the Office of Drug Safety regarding the manufacture and marketing of their pharmaceuticals in the U.S, including the filing of NDA 21-686 for Exanta and prior and subsequent meetings with the FDA in the U.S. regarding the NDA.

14. This Court may exercise personal jurisdiction over each Individual Defendant, because each purposefully directed his activities toward the U.S. and this litigation arises out of each Individual Defendant’s contacts with the U.S. By way of example, each Individual Defendant frequently traveled here on AstraZeneca business during the Class Period, including to participate in analyst and investor meetings and annual business reviews in the U.S.; defendants McKillop and Symonds signed and certified AstraZeneca’s Annual Reports on Form 20-F which were filed with
the Securities and Exchange Commission ("SEC") and contained the alleged misrepresentations; and/or each Individual Defendant has caused the distribution of false and misleading reports and statements to AstraZeneca investors in the U.S. Each Individual Defendant knew that AstraZeneca securities traded in the U.S., that its press releases were disseminated in the U.S. and that it regularly filed reports with the SEC, and that U.S. investors would rely upon them. In addition, each Individual Defendant made or caused to be made misrepresentations that had an effect in the United States, regardless of where they were made, by influencing U.S. investors or foreign investors who invest here. These effects were direct and foreseeable results of defendants’ misrepresentations. Each Individual Defendant thus has minimum contacts with the U.S., and the exercise of personal jurisdiction over each Individual Defendant would be reasonable.

15. Venue is proper pursuant to §27 of the Exchange Act as: (i) defendant AstraZeneca and/or the Individual Defendants’ wrongful conduct took place in this district; (ii) defendant AstraZeneca and/or the Individual Defendants conduct business in this district as AstraZeneca lists this district as its sales territory; and (iii) AstraZeneca and the Individual Defendants have stipulated to venue in this district.

THE PARTIES

16. Lead Plaintiff, State Universities Retirement System, purchased AstraZeneca’s publicly traded securities at artificially inflated prices on the NYSE and the London Stock Exchange during the Class Period, as detailed in the attached Certification, and was damaged thereby.

17. Defendant AstraZeneca develops drugs to treat cardiovascular and other disorders. The Company’s U.S. headquarters are located in Wilmington, Delaware. As of December 31, 2003, AstraZeneca had 1,692,694,946 ordinary shares outstanding and approximately 41,000 holders of ADRs outstanding. The ADRs, each of which is equivalent to one Ordinary Share, are issued by JPMorgan Chase Bank and trade on the NYSE under the symbol AZN.
18. Defendant Percy Barnevik ("Barnevik") serves as the Non-Executive Chairman of the Board of Directors of AstraZeneca. Barnevik is a citizen of the United Kingdom ("U.K.") and resides at 5 Lombardy Place, London W2-4AU, U.K.

19. Defendant Tom McKillop ("McKillop") served as Chief Executive Officer and Executive Director of AstraZeneca. McKillop is a U.K. citizen and resides at 5 Chester Cottages, Bourne, London SW1 W8HG, U.K.

20. Defendant Jonathan Symonds ("Symonds") served as Chief Financial Officer and Executive Director of AstraZeneca. Symonds is a U.K. citizen and resides at Batchworth Heath House, Rickmansworth, Hertfordshire, U.K., WD3 1QB.

21. Defendant Hakan Mogren ("Mogren") served as Deputy Chairman of the Board of Directors of AstraZeneca. Mogren is a Swedish citizen.

22. Barnevik, McKillop, Symonds and Mogren are referred to herein as the "Individual Defendants.

BACKGROUND TO THE CLASS PERIOD

Exanta, the Regulatory Approval Process and the Relevant Clinical Trials

23. Exanta, whose chemical name is ximelagatran, is an oral anticoagulant (blood thinner) which AstraZeneca began developing and testing in the 1990s. Exanta has never been approved for marketing by the FDA, and AstraZeneca ceased developing it altogether in February 2006.

24. Before a drug is submitted to the FDA or a foreign regulatory body for marketing approval, several phases of pre-clinical and clinical trials must first be completed to test the safety and efficacy of the drug. Pre-clinical trials are typically conducted in a laboratory environment prior to testing the drug in humans. "Phase I" clinical trials are small, controlled trials conducted to study the drug’s safety profile, including the safe dosage range, in humans. Phase I studies also determine
how a drug is absorbed, distributed and metabolized, as well as the duration of its action. “Phase II”
trials are controlled trials of volunteer patients to assess a drug’s effectiveness. “Phase III” trials, the
last stage of development prior to submission for marketing approval, involve patients in clinics and
hospitals, with physicians closely monitoring patients to confirm efficacy and to identify adverse
events. After a drug has completed one or more Phase III trials, the next step for marketing approval
in the U.S. is the submission of a NDA to the FDA, which includes all results of any relevant trials.
Once the NDA is accepted for filing, an FDA disciplinary review is commenced, to determine if
clinical trial and other data demonstrate that the drug is effective for its intended use and that the
established benefits of the drug outweigh its known risks.

25. By the beginning of the Class Period, AstraZeneca had completed or was nearing
completion of several clinical trials, involving tens of thousands of patients, that assessed the
efficacy of Exanta to prevent serious or fatal thromboembolism (blood clotting) in high risk patients.
Exanta was primarily tested against warfarin, marketed as Coumadin, the international gold standard
anticoagulation treatment. It is widely recognized in the medical community that there are several
disadvantages to treatment with warfarin, including the following: (1) warfarin does not take effect
for five days; (2) too much warfarin can cause excessive bleeding and too little provides no
therapeutic benefit, so that warfarin cannot be given in fixed doses, but rather every warfarin patient
must be monitored for blood coagulation and the drug dosage is adjusted accordingly; (3) warfarin
interacts with a very large number of drugs; and (4) common foods such as broccoli, brussels sprouts
and spinach can weaken the effect of warfarin. There was therefore a recognized need in the
medical community for an alternative to warfarin that could be given in fixed dosages, that did not
require coagulation monitoring and was not affected by other drugs or common foods. Defendants
assured investors that Exanta was a viable alternative to, if not a replacement for, warfarin.
26. Between 2000 and 2003, AstraZeneca conducted the following clinical trials of Exanta, four of which would form the basis of an NDA the Company would submit to the FDA seeking approval of the drug for the indications studied in each trial:

(a) **SPORTIF III and V** (acronym for “Stroke Prevention by ORal Thrombin Inhibitor in atrial Fibrillation): These Phase III trials compared the effectiveness of Exanta, taken for 12-26 months, to warfarin to prevent stroke and other thromboembolic complications in patients with atrial fibrillation (“AF”), or irregular heart rhythm. AF is a factor behind 15% of all strokes. SPORTIF III was an open label study conducted in 23 countries outside the U.S. on 3,407 patients. SPORTIF V was a blinded study conducted in the U.S. and Canada on 3,922 patients.

(b) **THRIVE Treatment and THRIVE III** (oral direct THRombin Inhibitor ximelagatran for Venous thromboEmbolism): These Phase III trials compared the effectiveness of Exanta, taken for 6 months (THRIVE Treatment) or 18 months (THRIVE III), to placebo in the long-term prevention of secondary venous thromboembolism (“VTE”) in patients who had suffered an episode of acute VTE and had been treated for 6 months with standard anti-coagulation treatment. VTE includes conditions of deep vein thrombosis (DVT) and pulmonary embolism (PE). The THRIVE trials were conducted on 3,733 patients.

(c) **EXULT A and B** (EXanta Used to Lessen Thromboembolism): These Phase III trials compared the effectiveness of EXANTA, taken for 7-12 days, to warfarin in preventing VTE and all-cause mortality following total knee replacement (“TSEK”) surgery. The EXULT trials were conducted on 4,604 patients.

(d) **ESTEEM**: This Phase II trial compared the effectiveness of varying doses of Exanta taken in combination with aspirin for six months to aspirin taken alone for six months in
preventing major cardiac events in patients who had suffered a heart attack. ESTEEM was conducted on 1,883 patients.

Liver Enzymes and Toxicity

27. Assessing liver abnormality requires measuring liver injury or inflammation as well as liver function. Liver injury is measured by levels of an enzyme known as alanine aminotransferase (commonly abbreviated as “ALT” or “ALAT”). Liver function is most commonly measured by assessing levels of bilirubin. Severe liver injury is commonly indicated in clinical practice as ALT levels of “greater than three times the upper limit of normal” (abbreviated “3 x ULN”) and total bilirubin levels of >2 x ULN. Based on a theory widely accepted in the medical community known as Hy’s Law, at least 10% of individuals with ALT > 3 x ULN and bilirubin > 2 x ULN will die from liver failure or require a liver transplant. A liver biopsy will frequently be helpful in differentiating patients who may progress to liver failure and death from those who are likely to recover from their injury.

28. Pharmaceutical drugs and a number of other factors can cause liver injury. Drug-induced liver injury is the leading reason why drugs are not approved by the FDA or are removed from the market.

The Importance of Exanta to Defendants and Investors

29. Throughout the Class Period, Exanta was one of AstraZeneca’s leading drugs in development, and was one of only a few new drugs in AstraZeneca’s pipeline of over 40 developmental products that were in Phase III clinical trials. Regulatory approval of Exanta in the United States and Europe was critical to the Company’s business and to investors, because in late 2001 and 2002, the U.S. patents expired on three of AstraZeneca’s drugs that, together, made up more than half of its sales: Prilosec, Zestril and Nolvadex. Prilosec alone generated sales of $6.26 billion in 2000, representing 39.6% of AstraZeneca’s total 2000 sales of $15.8 billion.
30. In an effort to boost investor confidence about future revenues and earnings, defendants embarked on a campaign to convince investors that the Company was successfully transitioning its portfolio from Prilosec and its older generation of drugs to late stage drugs in its development pipeline, in particular Exanta, Crestor and Iressa. Prior to and throughout the Class Period, defendants repeatedly pointed to AstraZeneca’s “portfolio transformation” in meetings with investors and analysts, specifically promoting Exanta, Crestor and Iressa as products that would replace lost Prilosec revenues.

31. However, setbacks in the FDA approval process for Iressa and Crestor during the summer of 2002 delayed these drugs’ approval, pushing out the time by which they would begin to generate profits. In January, 2003, the FDA notified the Company it needed still more time to review the NDA for Iressa. The FDA did not approve Iressa until May 2003, and did not approve Crestor until August 2003.

32. In the meantime, AstraZeneca’s revenues declined by over $3 billion in 2003 due to the loss of market share for Prilosec, Zestril and Nolvadex. Lost revenues on Prilosec contributed to the bulk of this decline. Global Prilosec sales declined from $5.68 billion in 2001 to $4.6 billion in 2002, then to about $2.6 billion in 2003 and to $1.8 billion in 2004.

33. The failure of Iressa and Crestor to begin generating revenues for the Company during the Class Period and the dramatic decline in Prilosec, Zestril and Nolvadez revenues made approval of Exanta even more important to defendants and investors. If approved, the market for Exanta would be in the billions of dollars. As defendants stated in a May 4, 2004 press release, “[t]he worldwide market for anticoagulants is around $4 billion and growing at 13 per cent annually,” and the worldwide market for antithrombotics, the drug class to which Exanta belonged,
“is around $12 billion, growing at 15 per cent annually.” Exanta sales were projected to be over $1.5 billion per year by 2007 if approved for marketing.

FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

34. Throughout the Class Period, defendants misrepresented what was discovered in the SPORTIF, THRIVE, EXULT and ESTEEM clinical trials about the safety, efficacy and risk-benefit profile of Exanta, as well as how it compared to warfarin as an anticoagulation treatment, as alleged in the following paragraphs.

35. On April 2, 2003, defendants announced selected results of SPORTIF III at the American College of Cardiology 52nd Annual Scientific Sessions in Chicago, Illinois and in a press release entitled “AstraZeneca’s Investigational Oral Anticoagulant Studied as Alternative To Well-Controlled Warfarin for Stroke Prevention In Atrial Fibrillation; Results of Largest Stroke Prevention Trial Presented at ACC,” which was issued from Wilmington, Delaware. The press release was also filed with the SEC as an exhibit to AstraZeneca’s Form 6-K filed May 12, 2003. Defendants made the following material representations in Chicago and in the press release:

Results of the largest stroke prevention trial ever conducted comparing AstraZeneca’s investigational oral anticoagulant EXANTA (ximelagatran) to warfarin in patients with nonvalvular atrial fibrillation (NVAF) were presented today at the American College of Cardiology 52nd Annual Scientific Session in Chicago.

In SPORTIF III … patients treated with EXANTA (n=1,704) had 40 strokes and systemic embolic events compared to 56 strokes and systemic embolic events in patients treated with warfarin (n=1,703). For those patients remaining on treatment throughout the trial (on treatment analysis), patients receiving EXANTA had 29 strokes and systemic embolic events compared to 52 events for patients on warfarin, a statistically significant relative risk reduction of 41 percent (p=0.018).

* * *

In the trial, 6.5 percent of patients treated with EXANTA experienced an increase to greater than three times the upper limit of normal of a liver enzyme called ALT, compared to 0.7 percent of patients in the warfarin group. Nearly all enzyme changes occurred within the first six months of treatment and decreased with or without drug discontinuation.
36. Following the Company’s April 2nd press release, Merrill Lynch reported it expected Exanta’s NDA to be filed in the third quarter of fiscal 2003, with a launch in early 2005 in the U.S. and Europe, and was predicting $1.3 billion in sales in 2007.

37. On April 7, 2003, a principal investigator for the SPORTIF III study for Exanta spoke on behalf of AstraZeneca during a conference call hosted by Merrill Lynch. The principal investigator was retained by AstraZeneca for the purpose of overseeing the study, and any statement or communication regarding the Company’s investigational products had to be approved and/or authorized by the Company. During the call, the principal investigator “confirmed that most cases with raised liver enzymes (ALAT) occurred between 2-6 months and tended to be transient. Even though bilirubin was raised in some patients, all cases were asymptomatic.” The principal investigator also said that liver monitoring “for a period of time would be adequate to protect patients from potential serious liver related disorders” and would be “infinitely preferable to the frequent monitoring associated with warfarin use.” Based on these comments, Merrill Lynch stated that it expected Exanta to “become a key driver in delivering EPS acceleration from 2004.”

38. Between April 2, 2003 and May 5, 2003, the Company’s ADR price increased over 16% from $36 to over $43 per share, its stock price on the Stockholm Stock Exchange increased from 292.50 SEK to 338.5 SEK, and its stock price on the London Stock Exchange increased from £22.65 to over £25.

39. Between May 14 and May 19, 2003, with the price of AstraZeneca’s stock artificially inflated, all four Individual Defendants sold over 61,653 shares of their AstraZeneca stock for proceeds of $2,632,485 when converted to U.S. dollars. Most notably, Barnevick, the Company’s non-executive chairman, sold 50,000 shares at 339.05 SEK per share for proceeds of $2,122,751.
40. Following these statements, AstraZeneca’s share price jumped 3.12 % on volume of over two million shares on the NYSE, increased 5.47% on the London Stock Exchange, and appreciated 5.04% on the Stockholm Stock Exchange.

41. On July 15, 2003, defendants announced selected results of the THRIVE Treatment study in a press release entitled: “Study shows new pill can treat life-threatening DVT without complications of current standard therapy.” Defendants made the following material representations in the press release:

In the THRIVE Treatment study, a fixed-dose of the tablet ximelagatran was as effective as the current complicated treatment combination of injected heparin [enoxaparin] plus warfarin tablets in preventing further DVTs or pulmonary emboli [PE].

* * *

As in real life, the dose of warfarin was adjusted in each patient on an ongoing basis to achieve a consistent and appropriate level of anticoagulation in their blood, which was measured in the usual way using INR. Ximelagatran does not require this kind of monitoring and is given at a fixed dose of 36 mg twice-a-day for VTE treatment in all patients. Treatment duration was six months. As part of the study protocol, liver enzymes were measured. The tests showed liver enzyme elevations in 9.6 per cent of patients on ximelagatran compared with 2.0 per cent of patients on the other treatment. These elevations decreased spontaneously whether ximelagatran treatment continued or stopped. As has been seen in previous studies, these elevations were typically transient and not associated with clinical symptoms.[1]

Ximelagatran is not yet available but is expected to be launched over the coming year. The THRIVE Treatment study is one of a number of different studies which, together, are establishing the effectiveness and safety of ximelagatran and providing understanding of how doctors could use it in the future.

42. Following the July 15, 2003, press release, AstraZeneca held an earnings conference call on July 24, 2003, carried on the Fair Disclosure Wire, in which defendants McKillop and Symonds described Exanta as a “breakthrough” drug:

TOM MCKILLOP: Maybe before we begin the q and a, I will say a word or two about Exanta(ph.). Exanta is the latest of our pipeline products to reach the critical
final stages of development. It is a breakthrough (indiscernible) class product in an area of high unmet need.

* * *

So potentially we have a very exciting product showing great efficacy in an area of huge medical need.

Now as we carried out this large critical program a fourth issue emerged. It became evident that a percentage of treated patients showed an elevation of liver enzymes. During a drug’s development any signal for hepato-toxicity must be taken very seriously. With excellent efficacy demonstrated, we believe that this is now the major remaining issue for Exanta and it will certainly be a key feature of the regulatory review.

* * *

Whilst I fully understand your desire to calibrate the liver contribution to the risk side of the benefit risk equation, it simply is not possible nor sensible for us to respond to highly detailed questions on individual pieces of the jigsaw at this stage.

* * *

What I will say is that based on the information available today and bearing in mind the excellent efficacy on the (indiscernable) of Warfarin, we believe that the risk benefit profile of Exanta remains strongly positive. However, I remind you again that it will only be when the analysis is complete that we, you and most importantly the regulators, will be able to judge where the final balance lies.

43. On July 28, 2003, defendants caused a press release entitled: “AstraZeneca’s Exanta Will Surpass $2.4 Billion in Sales in 2012, According to a New Study From Decision Resources” to be issued by Decisions Resources, Inc. (“DRI”), a market research company. AstraZeneca was a client of DRI. The press release stated in relevant part as follows:

Decision Resources, Inc., one of the world’s leading research and advisory firms focusing on pharmaceutical and health care issues, forecasts that AstraZeneca’s Exanta will revolutionize the prevention of stroke in cases of atrial fibrillation. Sales of Exanta will reach more than $1.5 billion in 2007 and surpass $2.4 billion in 2012.

Exanta offers many advantages over currently marketed oral anticoagulants like Bristol-Myers Squibb’s Coumadin—the current anticoagulant of choice for preventing stroke in atrial fibrillation. “Exanta can be given as a fixed oral dose,
without the need for titration or regular anticoagulant monitoring; it also has a superior food- and drug- interaction profiles,” said Ruth Brown, Ph.D., analyst at Decision Resources. “These advantages will not only allow Exanta to erode Coumadin’s market share, they will also allow the extension of anticoagulant therapy to a much wider patient population, including the elderly, who are often excluded from such treatment regimens because of physician concerns about Coumadin’s safety.”

44. On September 1, 2003, defendants announced results of the ESTEEM trial in a press release entitled: “Phase II study demonstrates promise for Exanta [ximelagatran] in reducing major cardiovascular events following myocardial infarction [MI].” The press release was also filed with the SEC as an exhibit to AstraZeneca’s Form 6-K filed October 1, 2003. Defendants made the following material representations in the release:

Results from ESTEEM show that oral Exanta significantly reduces the risk of death, recurrent heart attack or attacks of severe chest pain from 16.3% to 12.7% [all dose groups combined] during six months treatment in combination with aspirin, equating to a reduced risk of 24% [hazard ratio 0.76; p=0.036] compared with aspirin alone plus placebo.

“The results of this study are very exciting as they show the first proof of efficacy for Exanta in this new indication, and demonstrate that this new concept holds great promise for better protection against recurrent heart attacks in patients at risk of further cardiovascular events,” comments Professor Lars Wallentin, Professor of Cardiology at Uppsala University Hospital, Sweden, and Lead Investigator for the ESTEEM study.

Overall, a favourable safety profile was seen for Exanta in terms of bleeding and general adverse events. . . .

Laboratory blood tests in the study showed an increased incidence of liver enzyme elevations [see Note B] in patients receiving Exanta, compared with those receiving placebo, as observed in phase III studies. Elevated liver enzymes were seen in 6.5% of patients at the lowest dose, 24mg, while elevations were seen in 12.2 - 13% of patients at the higher doses. An incidence of elevated bilirubin levels > 2XULN combined with ALAT > 3XULN occurred in 0.6% of patients in the Exanta group, compared with 0.2% of patients in the placebo group. As seen in phase III Exanta studies, these ALAT elevations decreased towards baseline with treatment continuation or discontinuation and were not typically associated with specific clinical symptoms.
45. On September 2, 2003, defendants reported additional selected results for the SPORTIF III trial and reiterated results of the ESTEEM trial in a press release entitled: “Largest-ever stroke prevention study shows new tablet prevents strokes in patients with atrial fibrillation.” Defendants made the following material representations in the release:

Latest results from a study of 3,407 patients with non-valvular atrial fibrillation [AF, an irregular heart rhythm] show that ximelagatran is as effective in preventing strokes as warfarin, the current gold standard treatment.

* * *

Exanta[r] [ximelagatran], the first in a new class of oral direct thrombin inhibitors [DTIs], was found to compare favourably with warfarin for the prevention of stroke and blood clots at its fixed dose, 36mg twice daily [40 ximelagatran events versus 56 warfarin events].[5] The study shows that ximelagatran can be expected to be an effective, convenient replacement to warfarin.

* * *

. . . Standard lab tests measuring liver enzymes were included in the [SPORTIF] study design. Transient elevations in the levels of alanine aminotransferase [ALT] were observed in 6.3 per cent of patients receiving Exanta and an incidence of elevated bilirubin > 2XULN [upper limit of normal] combined with ALT > 3xULN was seen in 0.4 per cent of Exanta patients compared with 0.1 per cent of warfarin patients[1]. As in other Exanta phase III studies, these ALT elevations decreased towards baseline with treatment continuation or discontinuation and were not typically associated with specific clinical symptoms.

* * *

The ESTEEM trial also contributes to the growing evidence of ximelagatran’s favourable benefit-risk profile. Liver enzyme [ALT] elevations were also seen in this trial, but as in other studies, these ALT elevations decreased towards baseline with treatment continuation or discontinuation and were not typically associated with specific clinical symptoms. Elevated liver enzymes were seen in 6.5% of patients at the 24mg bd dose, with an incidence of 12.2 - 13% of patients at the higher doses [up to 60mg bd].

46. Also on September 2, 2003, defendants reiterated the SPORTIF III results alleged in the foregoing paragraph in a press release entitled: “Latest data from largest-ever stroke prevention
study in atrial fibrillation shows potential for Exanta [ximelagatran] in major indication.”

Defendants also made the following additional material representations in the release:

* * *

**Latest data from the full presentation of the SPORTIF III[1] study shows a net clinical benefit for Exanta[TM] [ximelagatran],** the first in a new class of oral direct thrombin inhibitors [oral DTIs], compared with the current standard treatment, dose-adjusted warfarin, in preventing stroke and systemic embolic events [SEE] in patients with atrial fibrillation [AF].

* * *

**The primary endpoint of SPORTIF III was met in demonstrating that fixed dose twice daily 36mg oral Exanta compares favourably with well-controlled dose-adjusted warfarin in prevention of stroke and SEE in patients with AF** [40 Exanta vs 56 warfarin events, ITT population].

* * *

Transient elevations in the levels of liver enzymes [alanine aminotransferase, ALAT] were observed in 6.3% of patients receiving Exanta and an incidence of elevated bilirubin > 2x ULN combined with ALAT > 3x ULN was seen in 0.4% of Exanta patients compared with 0.1% of warfarin patients. **As in other Exanta phase III studies to date, these ALAT elevations decreased towards baseline with treatment continuation or discontinuation and were not typically associated with specific clinical symptoms.**

“Data reported from SPORTIF III have underlined the overall clinical benefit and potential of Exanta in this important area of unmet medical need”, comments Dr Hamish Cameron, Vice President, Head of Exanta, AstraZeneca. “The results of SPORTIF III enhance the emerging benefit-risk profile for Exanta . . . .”

47. As a result of defendants’ positive reports about SPORTIF III and ESTEEM results, the price of AstraZeneca’s ADRs rose from a low of $39.22 per share on Friday, August 29, 2003 to $41.44 on September 3. The price of AstraZeneca’s stock also rose on the Stockholm Stock Exchange from 332.00 SEK on August 29 to 333.50 SEK on September 1, 335.00 SEK on September 2 and 342.50 SEK on September 3; and on the London Stock Exchange from £24.30 on August 29 to £25.02 on September 1, and from £24.85 on September 2 to £25.66 on September 3.
48. On October 2, 2003, AstraZeneca held its Annual Business Review in Wilmington, Delaware, at which several of the Company’s officers made very positive statements about the status of the Exanta launch. Defendant McKillop described the “market opportunity” for Exanta as “tremendous,” and said that “[w]e expect to achieve great things with” Exanta, whose expected launch in the U.S., along with a few other drugs in the pipeline, would keep AstraZeneca’s “business growing nicely in the mid-term.”

49. Hamish Cameron, Vice President of Exanta, gave a presentation about Exanta at the October 2 Business Review, during which he represented that in the SPORTIF III, ESTEEM and THRIVE studies, 17 of 4,988 patients treated with Exanta (.3%) had concomitant elevations of ALT and bilirubin compared to 3 of 4,267 patients treated with the comparator drugs (.07%).

50. Cameron also made the following material representations about Exanta during his presentation at the 2003 Annual Business Review:

I’m now going to update you on Exanta, a new entrance to the high potential antithrombotic market, which globally is currently valued at 10.8 billion and growing at 14%.

* * *

Our strategy is . . . to replace Warfarin and then expand use into new indications in patients, becoming the new gold standard in anticoagulation. . . . The desired profile was in contrast to Warfarin – to develop an oral anticoagulant without a narrow therapeutic index, allowing fixed dosing without the need for regular coagulation monitoring, further supported by a plan black (ph) of troublesome drug and food interactions. And all of this had to be achieved with an acceptable bleeding profile.

Today, after a clinical trial program with 30,000 patients, this profile has been delivered.

Through a series of large, mainly outcome trials, we’ve shown the target profile come to life in patients.

* * *
The common profile of Exanta has been strengthened by the results of SPORTIF III, the first pivotal trial of stroke prevention in AS patients. **SPORTIF III achieved the planned non-inferiority versus Warfarin.**

* * *

In longer termed studies of Exanta beyond 30 days, we’ve recorded raised liver enzymes. *Let me be clear at the outset. We believe Exanta has a positive benefit risk profile. And we’ll be presenting this case in our various regulatory submissions.*

* * *

We expect some form of liver function testing in Exanta labeling. Although for how long will be a matter for debate. *It should be no comparison with the complex and lifelong requirement for coagulation monitoring and dose titration in patients taking Warfarin.*

* * *

*For Exanta the enzyme elevations occur around two months…. They’re typically transient, not associated with specific symptoms and return to normal or baseline in respective of whether patients stop or continue the drug.*

* * *

There are many reasons why there’s so much interest in the potential value of Exanta. As you can see on this slide, managing anti-coagulation with Warfarin is a complex and costly process.

*And this isn’t the liver algorithm triggered in a few percent of patients. This is the monitoring for Warfarin used in every patient.*

* * *

[T]he one thing I would like to sort leave in your minds is that **Exanta (ph) is a product who’s benefit risk should be judged with your brain**, not your calculators.

[R]emember the burden of Warfarin. Remember all those patients who aren’t currently treated, who literally die because of that fact.

Then bring to the table the Warfarin comparative data that you’ve seen displayed repeatedly with good efficacy, good bleeding profiles. *Then you begin to put the liver data in context. So I would just repeat the statement: we’re very confident of a positive benefit risk profile for Exanta.*

* * *
We believe we have enough data to submit and enough data on which to make the compelling benefit risk case.

Sure, there’s an issue with liver enzymes. But through the risk management approach and the proper labeling of the product, we think – and the doctors we’ve worked with and the liver experts we’ve consulted – believe it is manageable.

* * *

We’ve followed up all the patients. You saw the recovery data on SPORTIF III. We’ve tracked them all with little green dots at the end of the line that will make a very good benefit risk case and a very solid safety base for FDA.

51. Following the Annual Business Review, between October 2 and 3, 2003, the prices of AstraZeneca’s securities rose from $43.25 to $46.49 on the NYSE, from 337.50 SEK to 354.50 SEK in Stockholm and from £26.04 to £27.12 in London.

52. On October 29, 2003, defendants announced the results of the EXULT A and THRIVE III trials in The New England Journal of Medicine and in a press release entitled: “Two Studies Published in the NEJM Report Effects of AstraZeneca’s Investigational Oral Anticoagulant EXANTA(TM) (ximelagatran) on Reducing Risk of Blood Clots,” which issued from Wilmington, Delaware and was published in the U.S. over PRNewswire. Defendants made the following material representations in the release:

Results of a Phase III clinical trial [EXULT A] of AstraZeneca’s investigational oral anticoagulant EXANTA(TM) (ximelagatran) showed that treatment with EXANTA (36 mg BID) reduced the risk of blood clots by 26 percent after total knee replacement (TSEK) surgery compared with dose-adjusted warfarin to a target INR of 2.5. Additionally, results from a second Phase III clinical trial [THRIVE III] in patients who had completed a conventional six-month course of treatment for blood clots showed that treatment with EXANTA for an additional 18 months resulted in about an 84 percent relative risk reduction of developing recurrent events compared with placebo.

* * *

Increases to greater than 3 times the upper limits of normal in the liver enzyme alanine aminotransferase (ALT) were observed with EXANTA compared to placebo (estimated cumulative risk at 18 months of 6.4 percent vs. 1.2 percent). These enzyme changes occurred within the first six months of treatment, were associated
with no specific clinical symptoms, and decreased with continuation or discontinuation of drug.

53. On October 29, 2003, the Company’s ADR price reached a high of $49.03 per share on the NYSE, and its stock price reached 375.50 SEK and £28.41 in Stockholm and London, respectively. On the same day, defendant McKillop sold another 5,482 shares of his securities at £28.57, about $48.51, per share for proceeds of $265,911.

54. On November 11, 2003, defendants announced selected results of SPORTIF V at the American Heart Association Scientific Sessions 2003 in Orlando, Florida and in a press release entitled: “New Landmark Study Confirms Potential for Exanta [ximelagatran] in Prevention of Stroke in Atrial Fibrillation,” which was published in the United States over PRNewswire Europe. Defendants made the following material representations in the release, and in substance in Orlando:

   Results from the SPORTIF V[1][a] study, presented today, support the potential for Exanta[TM] [ximelagatran], the first oral treatment in a new class of direct thrombin inhibitors [DTIs], to be an effective and predictable replacement for warfarin in the prevention of stroke and systemic embolic events [SEE] in patients with atrial fibrillation [AF], without the limitations of warfarin treatment. . . .

   SPORTIF V was designed as a non-inferiority[c] study to compare oral Exanta with the current standard treatment, dose-adjusted warfarin in preventing stroke and systemic embolic events [SEE] in atrial fibrillation, and the results support the findings of the SPORTIF III study. . . . The primary efficacy endpoint was met, showing that fixed dose twice daily 36mg oral Exanta is non-inferior to dose-adjusted warfarin in preventing stroke and SEE: 51 Exanta patients with events [1.6%/yr] vs 37 for warfarin [1.2%/yr], confirming non-inferiority based on the same criteria used in the SPORTIF III study. When the results from both studies are pooled, 91 patients with events were seen for Exanta compared with 93 for warfarin [1.6%/yr vs 1.6%/yr], supporting the efficacy of Exanta in prevention of strokes and thromboembolic events in patients with atrial fibrillation.

   *   *   *

   An elevation of liver enzymes [ALAT >3XULN] was observed in 6% of patients treated with Exanta in SPORTIF V, a consistent level to that seen in other long-term Exanta studies. An incidence of elevated bilirubin > 2XULN following ALAT > 3XULN was seen in 9 Exanta patients vs 1 warfarin patient. When assessed alongside SPORTIF III as pooled data, the overall incidence of liver
enzymes for Exanta in the SPORTIF programme is 6.1%, compared with 0.8% of patients in the warfarin group. These elevations are typically transient [occurring within first 2-6 months], decrease towards normal with treatment continuation or discontinuation and are not associated with specific clinical symptoms in the SPORTIF programme overall.

Overall, a statistically significant net clinical benefit is seen for Exanta from the pooled data of both the SPORTIF V and SPORTIF III studies. In an assessment of the combined rates of deaths, primary events and major bleeding while on treatment in both studies, 5.2% events were seen with Exanta compared with 6.2% with warfarin \( [p=0.038] \). This finding demonstrates that patients can benefit from a predictable and effective treatment to prevent morbidity and mortality, whilst avoiding the limitations that are associated with warfarin.

“SPORTIF V supports the overall clinical benefit of Exanta in this important area of unmet medical need,” comments Dr Hamish Cameron, Vice President, Head of Exanta, AstraZeneca. “The SPORTIF programme will represent the key element of our regulatory submissions supporting the use of the drug in the prevention of stroke and SEE in patients with atrial fibrillation.”

The nine patients with ALT > 3 x ULN and bilirubin > 2 x ULN brought the total disclosed number to 26.

55. On November 12, 2003, defendants reiterated results of SPORTIF V in a press release entitled: “AstraZeneca: New tablet hailed as major breakthrough in the prevention of strokes.” Defendants made the following material representations in the release:

Data presented today, showed that . . . . Exanta [ximelagatran], is as effective as warfarin at reducing strokes from blood clots in people with a common irregular heart rhythm called atrial fibrillation [AF]. Ximelagatran, the first direct thrombin inhibitor, has a consistent and reliable effect, therefore does not need time-consuming and resource-intensive anticoagulation monitoring to ensure patients achieve safe levels of anticoagulation. In addition, the same dose can be given to all patients and unlike warfarin, the effects of ximelagatran are not significantly influenced by food and alcohol and it has a low potential for interactions with other drugs.

* * * *

Liver enzyme [ALT] elevations were also seen in this trial, but as in other studies, these ALT elevations decreased towards baseline with treatment continuation or discontinuation and were not typically associated with specific clinical symptoms. Elevated liver enzymes were seen in 6% of patients at the 36 mg twice-daily dose compared with 0.8% of patients in the warfarin group.
56. As a result of defendants’ positive reports on the results of SPORTIF V and EXULT A, between November 11 and November 13, 2003, the prices of AstraZeneca’s securities rose from $46.11 to $47.70 on the NYSE, from 359.50 SEK to 362.00 SEK in Stockholm and from £27.36 to £27.67 in London.

57. On November 19, 2003, defendant Mogren sold another 8,792 of his AstraZeneca shares at 316.13 SEK, about $41.78, per share, for proceeds of $367,346.

58. On November 20, 2003, defendants reiterated selected results of SPORTIF III in a press release entitled: “Lancet Publishes Results of Largest Stroke Prevention Trial; AstraZeneca’s Investigational Oral Anticoagulant Studied as Alternative to Well-Controlled Warfarin for Stroke Prevention in Atrial Fibrillation,” which issued from Wilmington, Delaware and was published in the U.S. over PRNewswire. Defendants said, among other things, that Exanta achieved its primary endpoint of non-inferiority to warfarin in the prevention of strokes and systemic embolic events in SPORTIF III, and demonstrated a statistically significant relative risk reduction compared to warfarin of 41 percent. Defendants also reiterated that 6.3 percent of patients treated with EXANTA experienced an increase to greater than three times the upper limit of normal of the liver enzyme alanine aminotransferase (ALT), compared to 0.8 percent of patients in the warfarin group, but that “Nearly all enzyme changes occurred within the first six months of treatment and decreased with or without drug discontinuation.”

59. On December 6, 2003, defendants announced selected results of EXULT B at the 45th Annual Meeting of the American Society of Hematology (ASH) in San Diego, CA and in a press release entitled: “Phase III Study Reports the Results of AstraZeneca’s Investigational Oral Anticoagulant EXANTA(R) (ximelagatran) Following Total Knee Replacement (TSEK) Surgery,” which issued from Wilmington, Delaware and was published in the U.S. over PRNewswire.
Defendants said at the meeting and in the release that the incidence of total VTE and death was 22.5 percent in patients treated with Exanta, compared to 31.9 percent in patients treated with warfarin.

60. On December 9, 2003, defendants issued another press release regarding the ASH meeting and the results of EXULT B, titled: “Further Data Supports Safety and Efficacy of Oral Direct Thrombin Inhibitor, Exanta™ (Ximelagatran) in Prevention of Venous Thromboembolism,” which issued from London and was filed with the SEC as an Exhibit to AstraZeneca’s Form 6-K filed January 8, 2004. Defendants made the following material representations in the December 9 release:

AstraZeneca today announced further evidence to support the efficacy and safety profile of Exanta™ (ximelagatran), following a presentation at the American Society of Haematology (ASH) Annual Meeting 2003, San Diego, US.

* * *

Exanta was shown to provide superior efficacy to warfarin in preventing [VTE].

* * *

These results confirm the findings of EXULT A study . . . with both studies now showing that [Exanta] is clinically effective and superior to well-controlled warfarin in reducing total VTE and all-cause mortality among patients undergoing [TSEK].

61. On December 23, 2003, defendants announced in a press release that AstraZeneca had submitted an NDA with the FDA, seeking marketing clearance for EXANTA for three indications: (1) the prevention of VTE in patients undergoing TSEK surgery (which would be based on the results of the EXULT trials); (2) the prevention of stroke and other thromboembolic complications associated with AF (which would be based on the results of the SPORTIF trials); and (3) the long-term secondary prevention of VTE after standard treatment for an episode of acute VTE (which would be based on the results of the THRIVE III trial).

62. As a result of defendants’ positive reports about the Exanta trials and the filing of AstraZeneca’s NDA for Exanta, between December 22, 2003 and January 2, 2004, the prices of
AstraZeneca’s securities rose from $47.23 to $49 on the NYSE, from 344.50 SEK to 353.00 SEK in Stockholm and from £26.35 to £27.10 in London.

63. On February 10, 2004, while AstraZeneca’s securities were trading near their class period high, defendants completed a secondary placement of 21,200,000 shares of the Company’s stock in Sweden at 352 SEK per share, for about 7.5 billion SEK in proceeds (over $1 billion).

64. The Company’s ADR price rose to its Class Period high above $51 per share on March 10, 2004.

65. On March 12, 2004, AstraZeneca filed its Annual Report on Form 20-F for the year ended December 31, 2003 with the SEC, in which defendants made the following material representations:

Exanta, the first new oral anti-coagulant in almost 60 years, is a novel oral direct thrombin inhibitor targeted to prevent and treat the formation of blood clots (thrombosis). Exanta has been subject to the largest clinical study development programme in anti-coagulation to date, involving around 30,000 patients, and providing extensive outcome data. Several clinical studies with Exanta in prevention of stroke in patients with atrial fibrillation (SPORTIF III and SPORTIF V) and treatment of venous thromboembolism (VTE) (THRIVE Treatment) were presented during 2003. Liver enzyme elevations have been seen in a small proportion of patients treated with Exanta in chronic studies and are typically transient (occurring within the first two to six months), not associated with specific symptoms and tend to return towards normal whether or not treatment is continued. All data from the extensive clinical study programme has been shared with regulatory authorities to support a full evaluation of the benefit-risk profile for Exanta. The practical benefits of Exanta include fixed oral administration, rapid onset of action, low potential for drug/food and drug/drug interactions and no need for routine blood coagulation monitoring. A phase 2 study (ESTEEM) also indicates that Exanta provides additional benefits when added to standard therapy (including aspirin) in prevention of major CV events in patients following a heart attack.

66. Defendants McKillop and Symonds submitted written Certifications pursuant to §302 of the Sarbanes-Oxley Act of 2002 with AstraZeneca’s 2003 Form 20-F, certifying that: (1) they each reviewed the Form 20-F; (2) based on their knowledge, the Form 20-F did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements
made, in light of the circumstances under which they were made, not misleading; (3) they were each responsible for establishing and maintaining disclosure controls and procedures for the company; and (4) they had designed or caused to be designed such disclosure controls and procedures to ensure that material information relating to the Company is made known to them by others.

67. Defendants presented the following slide at the Exane Pharma Conference in Paris on May 10, 2004 highlighting Exanta’s success as one of the main products that would drive the Company’s replacement of lost Prilosec revenues:

![Successful portfolio transformation diagram]

68. At the Exane conference, defendants also presented the following slide, stressing Exanta’s virtues:
69. The same slides were presented and comments repeated at the HSBC SRI briefing in London on May 26, 2004 and at the Goldman Sachs Healthcare Conference in Dana Point, California on June 10, 2004.

70. On June 21, 2004, AstraZeneca announced that Exanta had been launched in Germany for short-term use in patients who had had orthopedic surgery.

**FDA INVESTIGATORS REPORT PREVIOUSLY UNDISCLOSED SAFETY AND EFFICACY DATA ON EXANTA**

71. Defendants submitted all results from the SPORTIF, THRIVE and EXULT trials, as well as other clinical trials, with its NDA filed with the FDA in December 2003. FDA personnel reviewed and analyzed all of the data submitted with the NDA and prepared reports on their findings for the FDA Cardiovascular and Renal Drugs Advisory Committee, who would make a recommendation to the FDA on whether or not to approve Exanta.

72. On September 9, 2004, the FDA posted the reports on its website in anticipation of a public meeting to be held on Friday, September 10, 2004 by the Advisory Committee to review AstraZeneca’s NDA for approval of Exanta. The reports did not represent the FDA’s opinion and
did not constitute recommendations on whether Exanta should be approved. Rather, they were intended to present an objective view of the clinical trial data to the Advisory Committee, who would make the ultimate determination on whether to recommend Exanta for approval. AstraZeneca representatives would also present data at the Committee meeting and would be given an opportunity to respond to any conclusions or data in the FDA reports.

73. The FDA reports revealed troubling, previously undisclosed data about the Exanta trials as alleged in the following paragraphs, all of which upset the drug’s risk-benefit and safety profiles and all of which was known to defendants throughout the Class Period.

**Risk of Severe Liver Injury**

74. The FDA’s review of data submitted by AstraZeneca revealed that long term use of Exanta (more than 35 days) presented a substantial risk of severe or fatal liver injury, and that defendants had previously misrepresented the magnitude of that risk and its ability to be managed. In particular, the FDA revealed for the first time the following facts:

(a) While defendants disclosed that some patients experienced increased ALT and bilirubin levels, they failed to disclose that 9 patients who received long-term treatment with Exanta died with concomitant increased bilirubin levels of >2 x ULN and ALAT levels >3 x ULN. Exanta-induced liver failure was determined to be the cause of or a contributor to three of those deaths, and the possible cause of or a contributor to the remaining six deaths. Whether Exanta did cause or contribute to the remaining deaths could not be determined because only one autopsy was performed in all nine deaths. Two of the nine patients died in late 2001, and upon information and belief, the remaining seven died before the beginning of and/or early in the Class Period;

(b) All nine patients who died were being monitored for liver enzyme levels, indicating that monitoring could not be relied upon to prevent serious or fatal liver toxicity;
(c) Liver enzymes did not return to normal after treatment was stopped in two of the patients whose deaths were deemed related to Exanta. One patient stopped treatment with Exanta when his ALT levels rose to 20 x ULN after three months, but his condition worsened; his ALT levels continued to rise, his bilirubin levels increased, and the patient died of liver failure. Another patient stopped treatment with Exanta after 24 days, but his condition continued to worsen afterward and he died from liver failure twenty days later;

(d) While defendants had reported a total of 26 cases of ALT > 3 x ULN/bilirubin > 2 x ULN in the long-term treatment trials (SPORTIF, THRIVE and ESTEEM), there were actually 37 such cases, all of which were classified as severe liver injury and nine of which were fatal. Thus, the FDA noted: “Higher incidence (0.53%) of severe liver injury (ALT >3x ULN + T. Bili. >2x ULN), including 3 deaths despite protocol specified LFT monitoring scheme;”

(e) Based on these results, it could be predicted that for every 100,000 patients treated with Exanta for longer than 35 days, 500 would develop severe liver injury. Accordingly, it could further be predicted based on Hy’s Law that 10% or 50 of the 500 Exanta patients who would develop severe liver injury (.05% of every 100,000) could be expected to die or require a liver transplant. The three liver related deaths that occurred in the long-term trials, in which 6,948 patients were treated with Exanta, were consistent with this prediction (one fatal liver injury occurred in every 2,300 patients); and

(f) Results from the trials established that compared to warfarin, Exanta posed a statistically significant relative risk of drug-induced severe liver injury (defined as ALT > 3 x ULN with bilirubin > 2 x ULN) of 8.5.

75. The percentages of severe liver injury and death seen in long-term Exanta patients was disturbingly high for a number of reasons. First, clinical trials are conducted on patient
populations that are much smaller than the number of patients who will actually be treated with a drug if approved. For example, less than 7,000 patients were treated long term with Exanta in the clinical trials, while millions of patients would be treated with the drug if approved. Three million patients per year are treated with warfarin and millions more are in need of anticoagulation treatment but left untreated. Exanta was expected to be prescribed for a large portion of that combined market or even to replace warfarin. Consequently, the number of patients who would be at risk for severe liver injury or death from Exanta was exponentially larger than in the clinical trials. Second, events of drug-induced liver injury have historically been more severe post-marketing than in clinical trials for a number of reasons, including failure or inability to adequately monitor liver enzymes in clinical practice and longer-than-recommended treatment duration. For example, Pfizer was forced to remove Rezulin, a diabetes drug, from the market because of liver problems after it was approved by the FDA. During the three years that Rezulin was on the market, 94 cases of liver failure were reported, while there had been no cases of acute or fatal liver failure during the drug’s clinical trials and only 2% of patients treated with Rezulin in clinical trials presented with ALT > 3 x ULN. Another drug, Duract, was removed from the market due to post-approval reports of liver transplants and death, while no cases of liver failure or death were seen in clinical trials and only .4% of patients presented with ALT > 3 x ULN.

76. Because of the risk of severe or fatal liver injury presented by Exanta, defendants were required by the FDA to submit a Risk Management Action Plan (“RiskMAP”) with the NDA for Exanta. Defendants proposed that the following monitoring program be required for patients treated with Exanta as part of the drug’s labeling: (1) monthly ALT screening for at least six months if a patient’s ALT remained < 2 x ULN; (2) weekly ALT monitoring if a patient’s ALT rose to > 2 x ULN; and (3) treatment if ALT rose to > 3 x ULN after four weeks or > 5 x ULN at any time.
Consequently, the fact that Exanta did not require coagulation monitoring was not an advantage over warfarin, because if Exanta were approved, patients would have to undergo stringent liver function monitoring.

77. The liver toxicity data from the trials greatly diminished, if not rendered non-existent, any potential market for the drug if approved.

**Risk of Coronary Artery Disease and Heart Attack**

78. In addition to the risk of irreversible severe or fatal liver toxicity, the short term (7-12 days) and long term use of Exanta presented a significantly higher risk of coronary artery disease adverse events, including acute myocardial infarction (heart attacks). While defendants disclosed that the combined rates of certain adverse events in Exanta patients was lower than or comparable to the comparator drugs in the various trials, they did not disclose that:

(a) in EXULT A and B combined (short term treatment), the proportion of patients who developed coronary artery disease was statistically significantly higher in the Exanta group than in the warfarin group: twenty of 2,677 patients treated with Exanta (.75%) developed coronary artery disease, compared to five of 1,907 patients treated with warfarin (.26%);

(b) the proportion of patients who had heart attacks in Exult A and B was also higher in the Exanta group: sixteen of 2,677 Exanta patients (.60%) suffered from heart attacks, compared to only 4 of 1,907 warfarin patients (.21%);

(c) in the long-term study population of patients being treated for VTE, the proportion of patients who developed coronary artery disease was statistically significantly higher in the Exanta groups than in the warfarin/placebo groups: 32 of 1,848 patients in the Exanta group (1.7%) developed coronary artery disease, compared to 12 of 1,859 patients (.7%) in the warfarin/placebo groups; and
(d) the proportion of VTE patients who suffered a heart attack was also significantly higher in the Exanta group: thirteen of 1,848 Exanta patients (.7%) suffered a heart attack compared to 3 of 1,859 warfarin patients (.16%).

79. The fact that the Exanta clinical trials demonstrated a 0.7%-1.7% risk of coronary artery disease or heart attack was material because Exanta was being developed as an anticoagulant with the potential to treat myocardial infarction, so that the drug’s potential to increase that risk was particularly troublesome. In addition, the population who would be treated with Exanta if approved was exponentially larger than the small clinical trial population, so that about 1 or 2 out of every 100 patients treated with Exanta would be at risk for a coronary adverse event.

**Exanta’s Efficacy Compared to Warfarin**

80. Exanta was not proven to be as effective as warfarin in preventing stroke and other complications in patients with AF. Defendants’ representations that Exanta was as effective as warfarin were based on an unreasonably liberal non-inferiority margin that was selected by AstraZeneca but not approved by the FDA for the SPORTIF trials. The non-inferiority margin chosen by AstraZeneca left open the possibility that Exanta was only half as effective as warfarin but still met the trial definition of “non-inferior.” Defendants’ representations about the “non-inferiority” of Exanta relative to warfarin were consequently false and misleading.

**Investor Reaction to the September 9 Reports**

81. In reaction to the September 9, 2004 disclosures, Prudential Equity Group, LLC, wrote: “AZN: FDA Documents on Exanta Look Downright Bad; Even Our Well-Below-Consensus Sales Forecasts Could Be Too High.” This report noted the FDA investigators’ concerns about efficacy and safety, and forecasted odds of approval at below 60%. Prudential analysts also observed that “[s]pending requirements necessary to launch this drug will come at a bad time for AZN - already the company is spending heavily to ‘defend’ Crestor . . . this pressures EPS.”
Analysts at Bear Stearns agreed. In their report of the same day, titled: “Exanta - Outright Rejection?” they pointed to safety concerns and concerns “new” to the market about the proportion of patients with coronary artery disease events. They also noted that the FDA calculated a 1 in 2,000 chance of liver failure, due to 9 deaths possible related to Exanta that were previously not reported.

82. Other analysts, such as Deutsche Bank and Citigroup, still expected approval. Citigroup, concluded, “[o]verall, the risk-benefit profile remains favorable in our view.”

83. As a result of the FDA’s September 9 reports and some analysts’ reactions, AstraZeneca’s stock and ADR prices declined on all three exchanges on very high trading volumes from September 8 to September 9, falling from $47.05 to $44.40 on volume of 12,673,100 shares on the NYSE; from £26.19 to £25.10 on volume of 32,852,316 in London; and from 352.50 SEK to 337.00 SEK on volume of 3,755,415 in Stockholm. Prices fell further on September 10 to $43.74 on the NYSE, £24.50 in London and to 334.50 SEK in Stockholm. Because the September 9 reports constituted only partial disclosures, however, the stock remained artificially inflated through September 10, as the Advisory Committee analyzed all available data, including reports prepared by AstraZeneca, in making its determination on approval.

THE FDA ADVISORY COMMITTEE SHEDS FURTHER LIGHT ON THE FDA REPORTS AND VOTES NOT TO RECOMMEND EXANTA

84. The September 10 FDA Advisory Committee meeting was attended by AstraZeneca representatives, including Hamish Cameron, M.D., Vice President, Exanta, Troy C. Sarich, Ph.D., Director, Clinical Pharmacology, Sunita Sheth, M.D., FAHA, Senior Director, Clinical Development, and Jay Horrow, M.D., MS, Senior Director, Clinical Development. At the September 10 meeting, the Advisory Committee and representatives of AstraZeneca and the FDA reviewed, explained and analyzed the data contained in the September 9 reports, providing a better understanding of the data and its significance to FDA approval. After a full day of discussion, the
Advisory Committee concluded that the FDA reports presented a more accurate and reliable view of the clinical trials than did AstraZeneca’s presentations. In particular, the Advisory Committee found that it could not be ruled out that the risk of stroke/SEE was in fact twofold greater in patients treated with Exanta compared to those treated with warfarin based on an analysis of AstraZeneca’s “non-inferiority” margin in the SPORTIF trials. Ultimately, the Advisory Committee determined that the clinical trials did not establish that Exanta was safe for long-term or short-term use due to liver-related injuries and coronary artery disease adverse events, or that Exanta was as effective as warfarin in preventing strokes in patients with AF. The Advisory Committee voted eleven to one against recommending FDA approval of Exanta.

85. After the publication of these facts, AstraZeneca was lambasted in the media for: (i) concealing the full extent of Exanta’s liver toxicity problems until the FDA briefing documents were published; (ii) not taking known liver toxicity problems seriously in its own testing; and (iii) not providing the FDA with real patient treatment options to the liver toxicity problems.

86. After the markets closed on Friday, September 10, 2004, defendants issued a press release entitled: “FDA Advisory Committee Recommends Further Data To Support Approval Of AstraZeneca’s Oral Anticoagulant Exanta™ (Ximelagatran),” which stated in relevant part that:

AstraZeneca today announced that the Cardiovascular and Renal Drugs Advisory Committee to the US FDA has advised that more data is needed to support the approval of the oral anticoagulant Exanta™ (ximelagatran).

Despite the Committee members’ recognition of the need for a new oral therapy to complement warfarin in the treatment of thrombotic disorders, the Committee advised that the indications for the prevention of strokes in patients with atrial fibrillation (AF), for the prevention of blood clots in patients undergoing knee replacement surgery, and for the long term secondary prevention of blood clots following standard treatment of a clot, should not be recommended on present data.

87. As a direct result of the news about the September 10 meeting, AstraZeneca’s securities continued to fall from Friday, September 10 to Monday, September 13 from $43.74 to
$41.80 on the NYSE, from £24.50 to £23.40 in London and from 334.50 SEK to 312.00 SEK in Stockholm.

88. On October 11, 2004, defendants announced in a press release that the FDA did not grant approval for EXANTA. In February 2006, AstraZeneca announced that it was ceasing any further development of the drug.

DEFENDANTS’ KNOWLEDGE OR RECKLESSNESS

89. The Individual Defendants had actual knowledge that each of the representations alleged herein were materially false and misleading when made and/or omitted material information based on the Company’s own submissions to the FDA, including: (a) the investigational drug application ("IND") for Exanta, submitted prior to the Class Period; (b) all protocols and protocol amendments for the Phase II and Phase III trials of Exanta; (c) internal reports and meetings regarding the results of all Exanta clinical trials; (d) the NDA and subsequent amendments to it; (e) correspondence, meetings and discussions between AstraZeneca and the FDA related to the NDA; and (f) the RiskMAP submitted with the NDA.

90. Defendants also had access to all relevant data rendering their Class Period representations false or misleading. All material data from each clinical trial was immediately and regularly reported to AstraZeneca and stored in a database designated for that specific trial. In particular, adverse events such as liver injury, coronary artery disease, heart attacks and death were required to be reported immediately to the Company on Serious Adverse Event ("SAE") forms. The data in each clinical trial database was categorized by multiple factors, including deaths and the causes of deaths of patients in the clinical trials, liver toxicity and related events, and coronary artery disease events. Statisticians employed by Exanta also analyzed all such data at the conclusion of each clinical trial and prepared comprehensive reports on the results of each trial within weeks of its
conclusion. The Individual Defendants were provided with summaries of these reports, including data on deaths and other serious adverse events, upon their completion.

91. In addition, prior to and throughout the Class Period, defendants had numerous meetings and other communications with the FDA and Office of Drug Safety in writing and via telephone regarding the risk of severe liver injury presented by Exanta, and in fact modified the study designs in response to ongoing liver toxicity results.

92. In or about June 2000, AstraZeneca implemented an amendment to its study designs requiring weekly monitoring of patients with ALT > 3 x ULN, and requiring discontinuation of treatment with Exanta if ALT rose above 7 x ULN. After the death of one patient in November 2001, another amendment was implemented, requiring weekly monitoring at ALT 2 x ULN, and discontinuation at 5 x ULN.

93. On July 14, 2003, a pre-NDA meeting was held between the FDA and representatives of AstraZeneca, at which the participants discussed, among other things, the fact that use of Exanta resulted in significant liver toxicity. For that very reason, a special meeting between AstraZeneca, the FDA and the Center for Drug Evaluation and Research’s Office of Drug Safety was held on October 9, 2003 to discuss a Risk Management Program for Exanta. AstraZeneca was thus required to submit, and did submit, a RiskMAP with its NDA for approval of Exanta in December 2003 to address the risk of hepatotoxicity associated with long-term use (35 days or more) of Exanta. The RiskMAP presented a plan to address the risk of severe liver injury associated with long-term use of Exanta by promoting compliance with ALT monitoring as part of the drug’s labeling. Defendants proposed that the following monitoring program be required for patients treated with Exanta as part of the drug’s labeling: (1) monthly ALT screening for at least six months if a patient’s ALT remained < 2 x ULN; (2) weekly ALT monitoring if a patient’s ALT rose to > 2 x ULN; and (3)
treatment if ALT rose to > 3 x ULN after four weeks or > 5 x ULN at any time. Defendants did not disclose the submission of RiskMAP when they announced the filing of the NDA in December 2003.

94. After submitting the NDA, AstraZeneca continued to communicate with the FDA throughout 2004 about its NDA and responded to several requests from the FDA for additional safety data regarding liver toxicity. During its communications with the NDA in 2004, AstraZeneca acknowledged that drug labeling and other methods to communicate laboratory monitoring recommendations, such as it proposed in RiskMAP, have historically been largely unsuccessful.

95. The Individual Defendants are also liable for the misrepresentations pleaded herein as they were “group-published” information. The Individual Defendants, because of their positions with the Company, had access to material non-public information concerning the Company’s day-to-day business. These Individual Defendants, through their direct involvement in the daily business of the Company, possessed the power and authority to control the contents of AstraZeneca’s quarterly and yearly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market, in the U.S. and abroad. Each defendant was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected.

INSIDER TRADING

96. The Individual Defendants sold at least 76,000 shares of their AstraZeneca stock on the London and Stockholm Stock Exchanges during the Class Period for total proceeds of about $3.27 million. As a foreign company listed on the U.S. Exchange, insiders were not required to file Forms 4 and other filings that notify investors of insider transactions. Defendants’ trading of which there is public knowledge is set forth below:
97. Defendants’ May 2003 sales were suspicious because they were timed to capture value at inflated prices and were coordinated with one another. Defendants Symonds, McKillop and Mogren all traded on the same day on May 19, 2003, just four days after defendant Barnevik sold 50,000 shares of his stock for proceeds of $2,122,751. Notably, the May trades occurred within two weeks after the Company’s ADR price increased by over 16% and shortly after the SPORTIF III results were first announced.

98. Six months later, McKillop and Mogren traded in close proximity again, McKillop reaping $265,911 on October 29, 2003, and Mogren reaping $367,346 on November 19, 2003. McKillop’s trading was suspicious because it occurred on the same day that the EXULT A and THRIVE III results were published and while the stock was trading very close to its Class Period high. Mogren’s trading was suspicious as it occurred within eight days after SPORTIF V results were first announced.

**LOSS CAUSATION/ECONOMIC LOSS**

99. In pursuing their claims pursuant to §10(b) and Rule 10b-5, plaintiffs invoke the presumption of reliance established by the fraud-on-the-market doctrine. In invoking the presumption of reliance, plaintiffs will show that:
(a) defendants made public misrepresentations and/or failed to disclose material facts to the public about Exanta during the Class Period;

(b) the omissions and misrepresentations about Exanta were material;

(c) the securities of AstraZeneca traded in open and efficient markets;

(d) the misrepresentations and omissions about Exanta induced reasonable investors to misjudge the value of AstraZeneca’s securities; and

(e) plaintiffs and other Class members purchased or otherwise acquired their AstraZeneca securities between the time defendants failed to disclose and misrepresented material facts, and plaintiffs were unaware of the true facts.

100. At all relevant times, the market for AstraZeneca’s securities was an efficient market, for the following reasons, among others:

(a) AstraZeneca’s shares traded on the NYSE, Stockholm and London Stock Exchanges, which are highly efficient and automated markets. Over 500 million AstraZeneca shares of common stock traded on the NYSE under the symbol AZN. Over 2.5 billion shares traded on the London Stock Exchange under the symbol AZNL. Over 440 million shares traded on the Stockholm Stock Exchange under the symbol AZNST. The high volume of shares traded is an indicator of market efficiency.

(b) As a regulated foreign issuer, AstraZeneca filed periodic public reports with the SEC. Specifically, as a foreign issuer, AstraZeneca filed annual reports (Form 20-F, the equivalent of a Form 10-K when issued by a U.S. company), quarterly reports (Form 6-K, the equivalent of a Form 10-Q when issued by a U.S. company), and registration statements (Form F-3, the equivalent of an S-4 when issued by a U.S. Company), during the Class Period.
(c) Defendants regularly communicated with public investors via established market communication mechanisms. This includes the Company’s regular dissemination of press releases on the national circuits of major newswire services, such as *Dow Jones*, *PRNewswire* and *Business Wire*. Defendants also communicated with its investors through other wide-ranging public disclosures, such as communications with the financial press like *Dun and Bradstreet*, *The New York Times*, and *Business Week*. Finally, defendants held regular conference calls to discuss AstraZeneca’s financial and operational performance on a regular basis.

(d) AstraZeneca was followed by numerous securities analysts employed by major brokerage firms, including, but not limited to, Merrill Lynch, Deutsche Bank, and others. These firms wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

101. As a result of the foregoing, the market for AstraZeneca’s securities promptly digested current information regarding AstraZeneca from all publicly available sources and reflected such information in AstraZeneca’s stock price. Because the stock price reflected all available information about the Company, defendants’ statements to the public regarding Exanta during the Class Period artificially inflated the stock and/or helped maintained the price at an artificially high level. Between April 2, 2003 and September 10, 2004, defendants repeatedly assured investors that Exanta had a compelling risk/benefit profile, and the Company’s stock price increased almost 32%. The AMEX Pharmaceuticals Index increased roughly 5% during the same time period.

102. As set forth in ¶¶33-70, defendants’ misrepresentations during the Class Period about the Exanta trials caused the Company’s stock price to be artificially inflated. Plaintiffs’ reliance on defendants’ statements about Exanta was reasonable.
103. However, the negative data from the trials that defendants concealed was exposed in September, 2004. The inflation began to leak out on September 9, 2004 when the FDA posted briefing documents on its website for the Advisory Committee to use at its September 10, 2004 meeting. The briefing documents revealed for the first time that defendants concealed or misrepresented material information about the safety and efficacy of Exanta. As a direct result of these revelations, AstraZeneca’s stock dropped 5.63% on the NYSE, 4.6% on the London Stock Exchange, and 4.4% on the Stockholm Stock Exchange from September 8 to September 9, and continued to drop on September 10, 2004, losing 1.49% on the NYSE, 2.39% on the London Stock Exchange, and .74% on the Stockholm Stock Exchange.

104. Then, after the close of the market on September 10, 2004, defendants revealed that the Advisory Committee overwhelmingly recommended that the FDA not approve Exanta based on an in-depth analysis of Exanta’s safety and efficacy. As a direct result of this news, on the next trading day, September 13, 2004, the stock suffered a 4.44% loss on the NYSE, a 2.39% drop on the London Stock Exchange, and a 6.73% decrease on the Stockholm Stock Exchange.

105. The stock price declines on September 9-13 were all directly related to the September 9 and 10 revelations about Exanta, and they removed the inflation from AstraZeneca’s stock price. As a result, investors who had purchased the stock at inflated prices during the Class Period suffered real economic loss. The timing and magnitude of these price declines negate any inference that the loss suffered by plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the defendants’ fraudulent conduct.

**INAPPLICABILITY OF STATUTORY SAFE HARBOR**

106. 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. The
statements alleged to be false and misleading herein all relate to then-existing facts and conditions. Moreover, the specific statements pleaded herein were not identified as “forward-looking statements” when made. To the extent that any of the statements identified herein as materially false and misleading are held by the Court to be forward-looking statements, there were no meaningful cautionary statements identifying important then-present factors that could, and indeed did, 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 those materially false forward-looking statements because at the time each of those 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 or director of AstraZeneca who knew that those statements were false when made.

CLASS ACTION ALLEGATIONS

107. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased AstraZeneca publicly traded securities (the “Class”) on the open market during the Class Period. Excluded from the Class are defendants, directors and officers of AstraZeneca and their families and affiliates.

108. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period AstraZeneca had more than 4 billion shares of stock outstanding, owned by thousands of individuals and entities.

109. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:
(a) Whether the Exchange Act was violated by defendants;
(b) Whether defendants omitted and/or misrepresented material facts;
(c) Whether defendants’ statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading; and
(d) Whether defendants knew or recklessly disregarded that their statements were false and misleading.

FIRST CLAIM FOR RELIEF
For Violation of §10(b) of the Exchange Act and Rule 10b-5
(Against All Defendants)


111. During the Class Period, defendants disseminated or approved the false statements alleged herein, which they knew or recklessly disregarded were materially false and misleading in that they contained material misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

112. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:
   (a) employed devices, schemes, and artifices to defraud;
   (b) made untrue statements of material facts or omitted to state material facts necessary in order to make 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 that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of AstraZeneca publicly traded securities during the Class Period.
113. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for AstraZeneca publicly traded securities. Plaintiff and the Class would not have purchased AstraZeneca publicly traded securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants’ misleading statements.

114. As a direct and proximate result of these defendants’ wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of AstraZeneca publicly traded securities during the Class Period.

SECOND CLAIM FOR RELIEF
For Violation of §20(a) of the Exchange Act
(Against the Individual Defendants)

115. Plaintiff incorporates 1-114 by reference.

116. The executive officers of AstraZeneca prepared, or were responsible for preparing, the Company’s press releases and SEC filings. The Individual Defendants controlled other employees of AstraZeneca. AstraZeneca controlled the Individual Defendants and each of its officers, executives and all of its employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the Exchange Act.

THIRD CLAIM FOR RELIEF
For Violation of Section 20A of the Exchange Act
(Against the Individual Defendants)


118. The defendants named in this claim sold AstraZeneca stock during the Class Period and Lead Plaintiff State Universities Retirement System purchased AstraZeneca stock contemporaneously with defendants’ sales. Specifically, defendant Barnevik sold 5,000 shares on the Stockholm Stock Exchange on May 14, 2003; defendant McKillop sold 4,944 shares on the London

119. By virtue of their senior positions at AstraZeneca and their participation in the scheme to defraud investors as described herein, defendants Barnevik, McKillop, Mogren and Symonds were in possession of material, non-public information about AstraZeneca at the time of their sales of AstraZeneca stock. Accordingly, these defendants violated the Exchange Act and applicable rules and regulations thereunder.

120. Plaintiffs and all other members of the Class who purchased shares of AstraZeneca securities contemporaneously with the sales of AstraZeneca securities by the defendants named in this Claim: (1) have suffered substantial damages in that they paid artificially inflated prices for AstraZeneca stock as a result of the violations of §§10(b) and 20(a) and Rule 10b-5 herein described; and (2) would not have purchased AstraZeneca at the prices they paid, if at all, had they been aware that the market prices were artificially inflated by defendants' false and misleading statements.

121. The AstraZeneca defendants are required to account for all such stock sales and to disgorge their profits or ill-gotten gains.

**PRAYER**

WHEREFORE, plaintiff prays for judgment as follows: declaring this action to be a proper class action; awarding damages, including interest; an accounting for and disgorgement of defendants’ insider sales; and such other relief as the Court may deem proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.
DATED: May 2, 2006

LERACH COUGHLIN STOIA GELLER
RUDMAN & ROBBINS LLP
SAMUEL H. RUDMAN (SR-7957)
DAVID A. ROSENFELD (DR-7564)

[Signature]
DAVID A. ROSENFELD

58 South Service Road, Suite 200
Melville, NY 11747
Telephone: 631/367-7100
631/367-1173 (fax)

LERACH COUGHLIN STOIA GELLER
RUDMAN & ROBBINS LLP
LAURA M. ANDRACCHIO
UDOKA NWANNA
655 West Broadway, Suite 1900
San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)

LERACH COUGHLIN STOIA GELLER
RUDMAN & ROBBINS LLP
LESLEY E. WEAVER
100 Pine Street, Suite 2600
San Francisco, CA 94111
Telephone: 415/288-4545
415/288-4534 (fax)

Lead Counsel for Plaintiffs
CERTIFICATION OF NAMED PLAINTIFF
PURSUANT TO FEDERAL SECURITIES LAWS

STATE UNIVERSITIES RETIREMENT SYSTEM OF ILLINOIS ("Plaintiff")
declares:

1. Plaintiff has reviewed a complaint and authorized its filing.
2. Plaintiff did not acquire the security that is the subject of this action at the
direction of plaintiff's counsel or in order to participate in this private action or any
other litigation under the federal securities laws.
3. Plaintiff is willing to serve as a representative party on behalf of the
class, including providing testimony at deposition and trial, if necessary.
4. Plaintiff has made the following transaction(s) during the Class Period in
the securities that are the subject of this action:

<table>
<thead>
<tr>
<th>Security</th>
<th>Transaction</th>
<th>Date</th>
<th>Price Per Share</th>
</tr>
</thead>
</table>

See attached Schedule A.

5. (a) During the three years prior to the date of this Certificate, Plaintiff
has served as a representative party for a class in the following actions filed under the
federal securities laws:
   In re Alstom SA Sec. Litig., No. 03-CV-6595(VM) (S.D.N.Y.) (lead plaintiff)
   In re Healthsouth Corp. Sec. Litig., No. CV-03-BE-1500-S (N.D. Ala.) (class representative)
   Ong v. Sears, Roebuck & Co., et al., No. 03 C 4142 (N.D. Ill.) (class representative)

   (b) Plaintiff is seeking to serve as a representative party for a class in
the following actions filed under the federal securities laws:

   (c) Plaintiff initially sought to serve as a representative party for a
class in the following actions filed under the federal securities laws, but either
withdrew its application or its application was denied in favor of other investors with
more significant losses:
   Fadem v. AOL Time Warner, Inc., et al., No. 1:02-CV-5575 (S.D.N.Y.)
   In re Cable & Wireless, PLC Sec. Litig., No. 02-1860-A (E.D. Va.)
   Marshall v. Peregrine Systems, Inc., et al., No. 02-CV-870(RBB) (S.D. Cal.)
6. The Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 24th day of March, 2005.

STATE UNIVERSITIES RETIREMENT SYSTEM OF ILLINOIS

By: _______________________

[Signature]

Its: General Counsel and

[Title]

ASTRAZENECA
### SCHEDULE A

SECURITIES TRANSACTIONS

#### Acquisitions

<table>
<thead>
<tr>
<th>Date Acquired</th>
<th>Type/Amount of Securities Acquired</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/02/2003 **</td>
<td>200</td>
<td>$41.04</td>
</tr>
<tr>
<td>05/02/2003 **</td>
<td>100</td>
<td>$41.59</td>
</tr>
<tr>
<td>05/02/2003 **</td>
<td>2,200</td>
<td>$41.59</td>
</tr>
<tr>
<td>05/02/2003 **</td>
<td>400</td>
<td>$42.24</td>
</tr>
<tr>
<td>05/05/2003 **</td>
<td>800</td>
<td>$41.50</td>
</tr>
<tr>
<td>05/08/2003 **</td>
<td>1,500</td>
<td>$40.79</td>
</tr>
<tr>
<td>05/07/2003 **</td>
<td>2,400</td>
<td>$40.65</td>
</tr>
<tr>
<td>05/08/2003 **</td>
<td>1,000</td>
<td>$41.91</td>
</tr>
<tr>
<td>05/13/2003 **</td>
<td>100</td>
<td>$42.20</td>
</tr>
<tr>
<td>05/15/2003 **</td>
<td>100</td>
<td>$42.92</td>
</tr>
<tr>
<td>05/16/2003 **</td>
<td>100</td>
<td>$43.84</td>
</tr>
<tr>
<td>05/16/2003 **</td>
<td>200</td>
<td>$43.84</td>
</tr>
<tr>
<td>05/19/2003 **</td>
<td>220</td>
<td>$42.72</td>
</tr>
<tr>
<td>05/22/2003 **</td>
<td>500</td>
<td>$40.45</td>
</tr>
<tr>
<td>05/26/2003 **</td>
<td>200</td>
<td>$40.83</td>
</tr>
<tr>
<td>05/29/2003 **</td>
<td>200</td>
<td>$40.42</td>
</tr>
<tr>
<td>05/29/2003 **</td>
<td>100</td>
<td>$40.86</td>
</tr>
<tr>
<td>06/03/2003</td>
<td>400</td>
<td>$40.19</td>
</tr>
<tr>
<td>06/04/2003</td>
<td>300</td>
<td>$41.09</td>
</tr>
<tr>
<td>12/30/2003</td>
<td>200</td>
<td>$40.39</td>
</tr>
<tr>
<td>01/02/2004</td>
<td>200</td>
<td>$40.88</td>
</tr>
<tr>
<td>01/06/2004</td>
<td>200</td>
<td>$48.52</td>
</tr>
<tr>
<td>01/09/2004 **</td>
<td>2,800</td>
<td>$48.49</td>
</tr>
<tr>
<td>01/07/2004 **</td>
<td>38,400</td>
<td>$48.19</td>
</tr>
<tr>
<td>01/07/2004</td>
<td>15,000</td>
<td>$48.23</td>
</tr>
<tr>
<td>01/08/2004</td>
<td>15,500</td>
<td>$48.31</td>
</tr>
<tr>
<td>01/09/2004</td>
<td>11,700</td>
<td>$48.17</td>
</tr>
<tr>
<td>01/12/2004</td>
<td>14,300</td>
<td>$48.58</td>
</tr>
<tr>
<td>01/13/2004 **</td>
<td>23,700</td>
<td>$47.00</td>
</tr>
<tr>
<td>01/13/2004</td>
<td>11,100</td>
<td>$46.05</td>
</tr>
<tr>
<td>01/14/2004</td>
<td>4,300</td>
<td>$47.51</td>
</tr>
<tr>
<td>01/15/2004</td>
<td>3,200</td>
<td>$46.36</td>
</tr>
<tr>
<td>01/16/2004</td>
<td>2,900</td>
<td>$47.07</td>
</tr>
<tr>
<td>02/12/2004 **</td>
<td>200</td>
<td>$48.18</td>
</tr>
<tr>
<td>08/31/2004 **</td>
<td>1,100</td>
<td>$45.67</td>
</tr>
</tbody>
</table>

#### Sales

<table>
<thead>
<tr>
<th>Date Sold</th>
<th>Type/Amount of Securities Sold</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/11/2003 **</td>
<td>6,987</td>
<td>$42.45</td>
</tr>
<tr>
<td>01/06/2004 **</td>
<td>2,900</td>
<td>$47.46</td>
</tr>
<tr>
<td>02/23/2004 **</td>
<td>800</td>
<td>$46.18</td>
</tr>
<tr>
<td>09/13/2004 **</td>
<td>1,700</td>
<td>$41.91</td>
</tr>
</tbody>
</table>

*Opening position of 101,180 shares.

**Ordinary shares converted to ADRs.
DECLARATION OF SERVICE BY UPS DELIVERY

I, the undersigned, declare:

1. That declarant is and was, at all times herein mentioned, a citizen of the United States and a resident of the County of San Diego, over the age of 18 years, and not a party to or interested party in the within action; that declarant’s business address is 655 West Broadway, Suite 1900, San Diego, California 92101.

2. That on May 2, 2006, declarant served by UPS, next day delivery, the AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS to the parties listed on the attached Service List.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 2nd day of May, 2006, at San Diego, California.

[Signature]

SUSAN L. HAMILTON
ASTRAZENECA (NY) (LEAD)
Service List - 5/2/2006 (05-0022N)
Page 1 of 1

Counsel For Defendant(s)

Michael P. Carroll
Joel M. Cohen
Patrick J. Murray
Davis Polk & Wardwell
450 Lexington Avenue
New York, NY 10017
212/450-4000
212/450-3800 (Fax)

John D. Donovan, Jr.
Gabriel D. O'Malley
Ropes & Gray LLP
One International Place
Boston, MA 02110-2624
617/951-7000
617/951-7050 (Fax)

Counsel For Plaintiff(s)

Lesley E. Weaver
Lerach Coughlin Stoia Geller Rudman & Robbins LLP
100 Pine Street, Suite 2600
San Francisco, CA 94111-5238
415/288-4545
415/288-4534 (Fax)

Samuel H. Rudman
David A. Rosenfeld
Lerach Coughlin Stoia Geller Rudman & Robbins LLP
58 South Service Road, Suite 200
Melville, NY 11747
631/367-7100
631/367-1173 (Fax)

Laura M. Andracchio
Udoka Nwanna
Lerach Coughlin Stoia Geller Rudman & Robbins LLP
655 West Broadway, Suite 1900
San Diego, CA 92101
619/231-1058
619/231-7423 (Fax)