CONSOLIDATED AMENDED COMPLAINT

Lead plaintiff the Mizla group (Joseph, Denise, Alan, Erin and Julia Mizla) (the “Mizla Group” or “Lead Plaintiff”) and plaintiffs James F. Corey, and Claire Spooner, by and through Lead Counsel, individually and on behalf of all others similarly situated, allege, based upon personal knowledge as to themselves and their own acts and, as to other matters, based on the investigation of counsel (which included a review of documents filed by defendants and their affiliates with the Securities and Exchange Commission (“SEC”), various news reports and articles and other publicly available information) as follows:

INTRODUCTION AND OVERVIEW

1. Lead Plaintiff and plaintiffs Corey and Spooner (collectively, “Plaintiffs”) bring this action on behalf of themselves and all other purchasers of the common stock of Discovery Laboratories, Inc. (“Discovery Labs” or the “Company”) between March 15, 2004 and June 6, 2006 (the “Class Period”) to recover damages that resulted from a series of false and misleading statements made by defendants concerning the Company’s ability to manufacture its
principal product, and the prospects for approval of that product by the relevant regulatory authorities.

2. Discovery Labs is a development stage biotechnology company, which is focused upon proprietary surfactant replacement technology. Surfactants are produced naturally in the lungs and are essential for breathing. The Company has indicated that its technology is intended to produce a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. This technology is designed for use as Surfactant Replacement Therapies ("SRT") for the treatment of respiratory diseases.

3. Throughout the Class Period, the Company's lead product, Surfacin®, was being prepared for submission to the FDA as part of a new drug application ("NDA") and to the European Medicines Evaluation Agency ("EMEA") under a Marketing Authorization Application for approval in Europe. Surfacin® is intended to treat and prevent Respiratory Distress Syndrome ("RDS") in infants. In addition, the Company was conducting various clinical trials of Surfacin® in other applications, including the prevention and treatment of Bronchopulmonary Dysplasia ("BPD," also known as Chronic Lung Disease) in premature infants, and for the treatment of acute respiratory disease syndrome ("ARDS") in adults. Discovery Labs was also preparing to conduct pilot studies with Aerosurf™, its proprietary aerosolized SRT administered
through nasal continuous positive airway pressure ("nCPAP"), for the treatment of neonatal respiratory failures.

4. Discovery Labs' Surfaxin® product was touted by the Company as highly promising, and Discovery Labs issued a series of public statements reporting on its progress through the regulatory approval process in the United States and in Europe.

5. A critical requirement for Discovery Labs to bring Surfaxin® to market in the United States was its ability to satisfy the FDA that it could manufacture the drug under relevant regulatory standards, which are known as current Good Manufacturing Practices. While the Company assured investors that it had established a contract manufacturing facility that could meet these requirements, defendants actually selected a facility that had been cited many times by the FDA for failure to comply with current Good Manufacturing Practices. When an inspection of the facility by the FDA revealed that this facility did not comply with current Good Manufacturing Practices, Discovery Labs issued disclosures indicating that the problems could be easily remedied.

6. After assuring the investing public that the problems at its contract manufacturing facility could be remedied readily, the Company issued disclosures at various times during the Class Period, indicating that formal FDA approval for Surfaxin® was expected to be received shortly. That did not happen.
7. First, on April 5, 2006, the Company revealed that approval for Surfacin® would not be forthcoming until additional conditions identified by the FDA were met. In response, the Company’s shares closed 29.16% lower.

8. Next, on April 24, 2006, the Company announced that it faced the potential of a significant delay in the approval process for Surfacin® because certain process validation batches manufactured for its NDA had not met required stability criteria during testing. Stability testing measures the ability of a pharmaceutical product to be stored without degradation, and stability testing is an element of current Good Manufacturing Practices that must be satisfied for a new drug application to receive regulatory approval from the FDA. In response, Discovery Labs’ common stock closed 53.09% lower the next day.

9. At various times during the Class Period, the Company also issued disclosures indicating that it anticipated approval of its Marketing Authorization Application by EMEA in the near future and stating that it was confident in the sufficiency of its data. Instead, the Company withdrew the application on June 6, 2006, and disclosed that withdrawal in a press release issued that day. This release indicated that there were “certain outstanding clinical issues.” On June 7, 2006, Discovery Labs’ common stock closed 19.28% lower in response to this news.

10. EMEA has since revealed that it had unresolved concerns with both the stability and the efficacy of Surfacin®. According to a recording made publicly available for replay, in a recent conference call with analysts on July 28,
2006, defendant Capetola explained that the Phase 3 clinical trials for Surfaxin® had been designed in close consultation with the FDA; that the scientific advice received from EMEA was different, and that the Company had elected not to perform clinical studies designed to meet EMEA’s clinical standards. When asked if one of the phase 3 clinical trials was sufficient for EMEA, defendant Robert J. Capetola responded: “No. It never was. We designed that with the FDA.”

11. During the Class Period, the Company raised over eighty million dollars through a series of financings. Meanwhile, defendant Robert J. Capetola, the Company’s Chief Executive Officer, and defendant Christopher J. Schaber, its Chief Operating Officer, disposed of a large number of shares of Discovery Labs common stock.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this action under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. §§ 1331, 1337, as this action arises under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. In connection with the wrongful acts alleged, defendants used the means of interstate commerce, including mail, interstate telephone, and the facilities of the NASDAQ Small Cap Market and the NASDAQ National Market System.

13. Venue is proper in this district under Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391, as the Company is based here, the
individual defendants transacted business here and the misleading disclosures
that are the subject of this action were disseminated from this district by the
defendants.

PARTIES

PLAINTIFFS

14. The Mizla Group is the Lead Plaintiff appointed by the Court under
Erin, and Julia Mizla. The individual members of the Mizla Group previously
filed certifications under the PSLRA with the Court, and all of their transaction
are set forth in the certification filed by Joseph Mizla.

15. Plaintiff Joseph Mizla is an individual who purchased 99,500 shares
of Discovery Labs common stock during the Class Period and was damaged by
reason of the wrongful acts alleged.

16. Plaintiff Denise Mizla is an individual who purchased 34,500 shares
of Discovery Labs common stock during the Class Period and was damaged by
reason of the wrongful acts alleged.

17. Plaintiff Alan Mizla is an individual who purchased 650 shares of
Discovery Labs common stock during the Class Period and was damaged by
reason of the wrongful acts alleged.

18. Plaintiff Erin Mizla is an individual who purchased 500 shares of
Discovery Labs common stock during the Class Period and was damaged by
reason of the wrongful acts alleged.
19. Plaintiff Julia Mizla is the trustee of the Julia Mizla Living Trust and the Cyril Mizla Family Trust, and she purchased, as trustee, 21,000 shares of Discovery Labs common stock during the Class Period and was damaged by reason of the wrongful acts alleged.

20. Plaintiff James F. Corey is an individual who purchased 39,000 shares of Discovery Labs common stock during the Class Period and was damaged by reason of the wrongful acts alleged. Plaintiff Corey’s transactions are set forth in his certification previously filed with the Court.

21. Plaintiff Claire Spooner is an individual who purchased 26,000 shares of Discovery Labs common stock during the Class Period and was damaged by reason of the wrongful acts alleged. Plaintiff Spooner’s transactions are set forth in her certification previously filed with the Court.

DEFENDANTS

22. Defendant Discovery Labs is a corporation organized under Delaware law with its principal place of business in Warrington, Pennsylvania. Discovery Labs’ common stock trades on the NASDAQ National Market System under the symbol DSCO. Prior to June 30, 2004, its common stock traded on the NASDAQ Small Cap Market.

23. Defendant Robert J. Capetola ("Capetola") has been the President, Chief Executive Officer and a director of Discovery Labs since 1998.

a. Employment History. Prior to 1998, defendant Capetola was the Chairman and Chief Executive Officer of Acute Therapeutics, Inc. ("ATI"), a
majority-owned subsidiary of the Company. Defendant Capetola held previous positions at Delta Biotechnology, Ohmeda Pharmaceutical Products Division, a unit of The BOC Group, and Johnson & Johnson Pharmaceutical Research Institute.

b. **Education.** According to the Company's proxy statement filed with the SEC on April 2, 2004, defendant Capetola received his B.S. from the Philadelphia College of Pharmacy & Science and his Ph.D. in pharmacology from Hahnemann Medical College.

24. Defendant Christopher J. Schaber ("Schaber") was employed by the Company from November 1996 to May 2006. During the bulk of the Class Period, defendant Schaber was the Company's Executive Vice President and Chief Operating Officer with the responsibility for clinical development, medical affairs, regulatory affairs, quality assurance and manufacturing and distribution. On May 4, 2006, the Company announced that it had terminated defendant Schaber's employment contract.

a. **Employment History.** Previously, defendant Schaber was the Company’s Executive Vice President of Drug Development and Regulatory Compliance, commencing in April 1999, and its Chief Development Officer and Vice President of Regulatory Affairs and Quality Assurance/Quality Control, commencing in June 1998. Defendant Schaber served as Vice President of Regulatory Affairs and Quality Assurance with ATI from 1996 to 1998.
b. **Education.** According to the Company's proxy statement filed with the SEC on April 2, 2004, defendant Schaber received his B.A. from Western Maryland College and his M.S. in Pharmaceutics from Temple University. Defendant Schaber received his Ph.D. in Pharmaceutical Sciences with The Union Graduate School in July 2003 and holds a Regulatory Affairs Certification from the Regulatory Affairs Professional Society.

**CLASS ACTION ALLEGATIONS**

25. Plaintiffs bring this action as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of all persons who purchased common stock of Discovery Labs between March 15, 2004 and June 6, 2006 (the "Class"). Excluded from the Class are defendants, members of their families, and the directors and officers of Discovery Labs and its subsidiaries.

26. Throughout the Class Period, Discovery Labs shares traded in an open, developed and efficient market. The Company's shares initially traded on the NASDAQ Small Cap Market. From June 30, 2004 to date, its shares have traded on the NASDAQ National Market System. Discovery Labs was followed by analysts, and its stock price fluctuated in response to announcements made concerning its business operations and the prospects for approval of its principal product by regulatory authorities. The Company was eligible to register securities using Form S-3, and it did so at various times during the Class Period.

27. The members of the Class are so numerous that joinder of all of them is impracticable. While the precise number of members is not known to
Plaintiff at the present time, the Company's stock traded actively during the Class Period, and there are likely to be thousands of members of the Class.

28. There are questions of law or fact common to the Class, including the following:

   a. whether defendants' public statements about the business operations of Discovery Labs and the prospects for approval of its principal product were materially false and misleading;

   b. whether defendants participated in and pursued the common course of conduct alleged;

   c. whether defendants acted with scienter;

   d. whether the market price of Discovery Labs common stock was artificially inflated during the Class Period by reason of the defendants' wrongful acts; and

   e. the extent of the damages recoverable by members of the Class.

29. Plaintiffs' claims are typical of the claims of the members of the Class, as they purchased Discovery Labs common stock during the Class Period while it traded at artificially inflated prices by reason of the defendants' false and misleading disclosures.

30. Plaintiffs are representative parties who will fairly and adequately protect the interests of the Class; they have retained counsel experienced and competent in both class actions and securities litigation, generally. Plaintiffs
have no interests that are contrary to or in conflict with those of the members of the Class.

31. The questions of law and fact common to the members of the Class predominate over any questions which affect only individual members.

32. A class action is superior to other available methods for the fair and efficient adjudication of this controversy, as many members of the Class will have damages arising from defendants' wrongful course of conduct that would not be susceptible to individualized litigation because of the cost associated with complex litigation of this kind.

FACTUAL BACKGROUND

DISCOVERY LABS

33. Discovery Labs is a development stage biotechnology company: it has no products that are currently available for sale to the public. Instead, it has potential products in various stages of the regulatory approval process.

34. As a development stage biotechnology company, Discovery Labs historically has been expending funds generated through equity offerings on the development of its products and has not generated significant revenues through operations. Analysts who follow development stage biotechnology companies regularly focus on their "cash burn rate" and their ability to raise additional debt or equity financing. As the Company noted in its Form 10-Q for the third quarter of 2003, "[w]e will need substantial additional funding to conduct our business, including our expanded research and product development activities." Because
the Company was in the development stage and had to raise equity financing periodically to continue operations, its common stock was particularly volatile.

35. As is common in development stage companies, the officers and directors have significant shareholdings, and a major component of their compensation is in the form of stock options. According to the Company’s proxy statement, filed with the SEC on April 2, 2004, defendant Capetola held 888,072 shares of Discovery Labs common stock as of March 10, 2004 and had options for another 657,500, giving him beneficial ownership of 3.47% of the Company’s common stock. The April 2004 proxy statement indicated that defendant Schaber held 207,145 shares outright and had options for 415,344 shares, giving him beneficial ownership of 1.41% of the Company’s common stock. Defendants Capetola and Schaber entered into long-term forward contracts, selling large quantities of their holdings, at times relevant to this action.

36. The Company’s development efforts were focused upon a synthetic surfactant technology invented by the Scripps Research Institute and initially developed by Johnson & Johnson. Discovery Labs acquired an exclusive sublicense to the technology in 1996.

SURFACTANT REPLACEMENT THERAPY

37. Surfacin®, the Company’s lead product, is an artificial surfactant which is comprised of four active ingredients: sinapultide, dipalmitoylphosphatidylcholine, palmitoyl-oleoyl phosphatidylglycerol and palmitic acid. The use of four active ingredients is somewhat unusual. Most drugs contain a
single active ingredient that is mixed with one or more non-reactive substances, which are referred to as excipients. According to the Company’s annual report on Form 10-K filed with the SEC on March 15, 2004, the four separate active ingredients came from different suppliers: sinapultide was furnished at relevant times by BACHEM California, Inc. and PolyPeptide Laboratories, Inc; the other ingredients were provided by a variety of other suppliers, including Genzyme Pharmaceuticals, and Avanti Polar Lipids.

38. In its annual report on Form 10-K filed on March 15, 2004, Discovery Labs described surfactants as follows:

Surfactants are protein and lipid (fat) compositions that are produced naturally in the lungs and are critical to all air-breathing mammals. They cover the entire alveolar surface, or air sacs, of the lungs and the terminal conducting airways which lead to the air sacs. Surfactants facilitate respiration by continually modifying the surface tension of the fluid normally present within the alveoli, or air sacs, that line the inside of the lungs. In the absence of sufficient surfactant or should the surfactant degrade, these air sacs tend to collapse, and, as a result, the lungs do not absorb sufficient oxygen. In addition to lowering alveolar surface-tension, surfactants play other important roles in human respiration including, but not limited to, lowering the surface tension of the conducting airways and maintaining airflow and airway patency (keeping the airways open and expanded). Human surfactants include four known surfactant proteins, A, B, C and D. It has been established, through numerous studies, that surfactant protein B (SP-B) is essential for respiratory function.

39. The Company’s 2004 10-K described the existing surfactant products as follows:

Presently, the FDA has approved surfactants as replacement therapy only for Respiratory Distress Syndrome in premature infants, a condition in which infants are born too soon and thus
have an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from pig and cow lungs. Though they are clinically effective, they have drawbacks and cannot readily be scaled or developed to treat broader populations for Respiratory Distress Syndrome in premature infants and other respiratory diseases. There is presently only one approved synthetic surfactant available, however, this product does not contain surfactant proteins, is not widely used and is not actively marketed by its manufacturer.

Animal-derived surfactant products are prepared using a chemical extraction process from minced cow and pig lung. Because of the animal-sourced materials and the chemical extraction processes, there can potentially be significant variation in production lots and, consequently, product quality specifications must be broad. In addition, the protein levels of these animal-derived surfactants are inherently lower than the protein levels of native human surfactant. The production costs of these animal-derived surfactants are high, relative to other analogous pharmaceutical products, generation of large quantities is severely limited, and these products cannot readily be reformulated for aerosol delivery to the lungs.

40. The 2004 10-K outlined the potential advantages of the Company’s products in these terms:

Our humanized surfactant product candidates, including Surfaxin, are engineered versions of natural human lung surfactant and contain a humanized peptide, sinapultide. Sinapultide is a 21 amino acid protein-like substance that is designed to closely mimic the essential attributes of human surfactant protein B (SP-B), the surfactant protein that is most important for the proper functioning of the respiratory system. Our products have the ability to be precisely formulated, either as a liquid instillate, aerosolized liquid or dry powder, to address various medical indications.

41. In November of 2003, Discovery Labs announced that it concluded Phase 3 clinical trials for Surfaxin® that were required as support for an NDA seeking approval to market Surfaxin® for RDS. In a release dated November 25,
2003, the Company reported that two Phase 3 trials had been concluded successfully. One study tested Surfaxin® against Exosurf, a non-protein based synthetic surfactant, with Survanta, a cow-based product, serving "as a reference arm." The November 25, 2003 release noted that the Company had recently reported on another supportive Phase 3 clinical trial, designed as a non-inferiority trial, which compared Surfaxin® to Curosurf, a pig-based product that many neonatologists believed was the best currently approved product.

42. The study that compared Surfaxin® to Exosurf was known as the SELECT trial, while the study comparing Surfaxin® to Curosurf was known as the STAR trial.

DISCOVERY'S MANUFACTURING ARRANGEMENTS

43. To gain FDA approval for its Surfaxin® NDA, Discovery would need to demonstrate that it had the means to manufacture and distribute its product. The FDA regulates the manufacture of prescription drugs through the imposition of certain standards known as current Good Manufacturing Practices. To obtain approval to market Surfaxin®, the Company would need to demonstrate that it could manufacture Surfaxin® in compliance with these FDA standards.

44. Discovery Labs added staff to supervise manufacturing, which was defendant Schaber's responsibility. On July 17, 2003, Discovery Labs announced that it had hired Ronald J. Ritz to serve as Vice President, Manufacturing Operations. The release indicated that Mr. Ritz had 25 years of relevant
experience, including senior positions at Elan Pharmaceuticals and Johnson & Johnson. The release quoted defendant Schaber, who indicated that Mr. Ritz had extensive experience in manufacturing, compliance with FDA standards and managing facility inspections.

45. Discovery Labs did not own any manufacturing facilities, since it had been focused upon product development. Instead, the Company had relied upon contract manufacturers. It initially used Akorn, Inc. as a contract manufacturer, but Akorn experienced production difficulties that had delayed a Phase 2 clinical trial for Surfaxin® in 2002.

46. To address its manufacturing needs, Discovery selected a new contract manufacturer, Laureate Pharma L.P. (“Laureate”), a Delaware Limited Partnership affiliated with Purdue Pharma L.P. (“Purdue”). The Company announced the arrangement in a press release dated August 12, 2003, which stated that Laureate had “cGMP-compliant manufacturing facilities in Princeton and Totowa, New Jersey and a successful history of producing sterile pharmaceutical and biopharmaceutical products.” Discovery Labs finalized this arrangement in October 2003, entering into a Technology Transfer and Manufacturing Agreement with Laureate dated October 3, 2003.

47. The facility Laureate was to dedicate to manufacturing Surfaxin® was located in Passaic County at 700 Union Boulevard, Totowa, N.J. (the “Totowa Facility”). The Totowa Facility had previously been operated by Purdue, and by Purdue’s affiliate, The P.F. Laboratories, Inc. (“P.F. Labs”). The
Totowa Facility had a troubled history: Purdue and P.F. Labs had each received FDA Form 483 Reports and Warning Letters concerning the failure of the Totowa Facility to conform with current Good Manufacturing Practices.


49. Among the problems identified by the FDA were inadequate controls in the quality control unit to assure that all data was collected, inadequate manufacturing process records, laboratory tests that were performed without sufficient documentation, inadequate raw material and in-process controls, use of ingredients that had not been qualified for use by the FDA, failure to invalidate batches of drugs that failed stability testing, failure to follow established stability testing protocols, compound specifications that failed to address known impurities, and inadequate manufacturing process validation. These Form 483 reports addressed P.F. Labs' operations in manufacturing both its own products and products it produced as a contract manufacturer for other companies, and they were readily available to defendants from the FDA.

50. On March 23, 1998, the FDA issued warning letter no. 98-NWJ-18 to P.F. Labs, noting that the response to a prior Form FDA-483, which related to an inspection of the Totowa Facility conducted from February 4, 1998 through
February 23, 1998, was deemed inadequate and that drug products manufactured there were deemed to be adulterated. The problems cited included inadequate quality controls. On November 9, 2001, the FDA issued warning letter No. 02-NWJ-18 to Purdue, indicating that its response to a prior Form FDA-483, which related to an inspection of the Totowa Facility between June 12, 2001 through July 6, 2001 and from July 30, 2001 through September 21, 2001 was inadequate and that products being produced at that facility were deemed to be adulterated. Among the issues raised were inadequate quality controls. These warning letters were readily available to the defendants from the FDA.

**FINANCING AND MARKETING ARRANGEMENTS**

51. Because it was a development stage biotechnology company, Discovery Labs needed access to sufficient financing to sustain its operations pending approval of its products for sale. The Company also needed to develop the means to bring its products to market if they were approved by the relevant regulatory authorities in the United States and Europe. As of the beginning of the Class Period, the Company had existing relationships with a variety of entities that were intended to meet those needs.

52. Discovery Labs had a strategic alliance with Quintiles Transnational Corp. ("Quintiles"), and its affiliate, PharmaBio Development Inc. ("PharmaBio"), to provide certain commercialization services in the United States. Under this arrangement, Quintiles was obligated to hire and train a dedicated United States sales force that would be held out as that of Discovery
Labs. PharmaBio agreed to fund up to $70 million of the sales force costs, as well as other sales and marketing costs for commercialization of Surfaxin® in the United States for seven years. PharmaBio also provided the Company with a secured revolving credit facility of up to $8,500,000 to $10,000,000 to fund pre-marketing activities associated with the launch of Surfaxin® in the United States, subject to certain milestones.

53. To address its needs in foreign markets, the Company had a strategic alliance with Laboratorios del Dr. Esteve, S.A. ("Esteve") to develop, market and sell Surfaxin® throughout Europe and Latin America. Under this arrangement, Esteve was obligated to buy all of its Surfaxin® from Discovery Labs and to support certain development costs for clinical trial costs. Esteve’s payment obligations were tied to certain milestones as well.

54. To obtain financing, the Company had, from time-to-time, issued shares of its common stock or other securities in both public and private offerings. As of the beginning of the Class Period, the most recent equity financing by the Company was a June 30, 2003 private placement, which had raised net proceeds of $25,900,000. On December 19, 2003, Discovery Labs filed a registration statement on Form S-3 for 6.5 million shares of its common stock. This was a shelf registration that authorized the Company to issue the registered shares from time to time.
DEFENDANTS CAPETOLA AND SCHABER SELL THE COMPANY'S STOCK

55. At times relevant to this action, defendant Capetola and defendant Schaber decided to make long-term bets against the Company, entering into forward contracts in 2004 for the sale of Discovery Labs common stock which would be delivered in 2006 (for Capetola and Schaber) and in 2007 (for Capetola). Each of these transactions was the economic equivalent of a short sale.

56. According to a Form 4 filed with the SEC on January 26, 2004, defendant Capetola directly owned 886,747 shares of Discovery Labs common stock as of January 23, 2004. On February 27, 2004, shortly before the beginning of the Class Period, defendant Capetola entered into a two-year variable prepaid forward contract. Under the terms of the contract, defendant Capetola was paid $4,774,639.59 in return for an agreement to deliver between 377,825 shares and 472,269 shares of Discovery Labs common stock on February 27, 2006. The contract also gave him the option to settle the transaction by delivering cash equivalent to the required number of shares on February 27, 2006.

57. Defendant Capetola disposed of between 42.60% and 53.28% of his directly owned shares in this transaction, which was disclosed by a Form 4 filed with the SEC on March 2, 2004. Defendant Capetola showed great foresight: on February 27, 2004, the closing price for Discovery Labs common stock was $12.00 per share; on February 27, 2006, the closing price for Discovery Labs common stock was $7.67.
58. On March 18, 2004, the fourth day of the Class Period, defendant Capetola entered into a second forward contract for the sale of Discovery Labs common stock. Under this transaction, defendant Capetola was obligated to deliver between 230,784 and 300,000 shares of Discovery Labs common stock on March 18, 2007. The contract also gave him the option to settle the transaction by delivering cash equivalent to the required number of shares on March 18, 2007.

59. Defendant Capetola disposed of between 23.02% and 33.83% of his directly owned shares in this transaction, which was disclosed by a Form 4 filed with the SEC on March 22, 2004. The closing price of Discovery Labs common stock on March 18, 2004 was $11.90. Defendant Capetola received net proceeds of $3,159,000 from this transaction.

60. According to a Form 4 filed with the SEC on March 3, 2004, defendant Schaber directly owned 207,145 shares of Discovery Labs common stock as of March 1, 2004. On April 7, 2004, defendant Schaber entered into a two year variable prepaid forward contract, which obligated him to deliver between 171,562 and 205,820 shares of Discovery Labs common stock on April 7, 2006. The contract also gave him the option to settle the transaction by delivering cash equivalent to the required number of shares on April 7, 2006.

61. Defendant Schaber disposed of between 82.82% and 99.03% of his directly owned shares in this transaction, and he received net proceeds of $2,311,359. Defendant Schaber also showed great foresight: the closing price of Discovery Labs common stock on April 7, 2004 was $12.44; on April 7, 2006, the
Company's common stock closed at $4.36. Defendant Schaber disclosed his forward contract with a Form 4 filed with the SEC on April 12, 2004 and an amended Form 4 filed April 14, 2004.

**EVENTS OCCURRING DURING THE CLASS PERIOD**

62. Commencing on March 15, 2004 (the first day of the Class Period), and continuing through June 6, 2006 (the last day of the Class Period), Discovery Labs issued a series of press releases and SEC filings that were materially false and misleading. The disclosures were materially false and misleading because they falsely portrayed the Company's capacity to manufacture its principal product in compliance with the FDA's current Good Manufacturing Practices, a requirement it had to meet before the FDA would grant approval to that product. At various times, defendants' public statements also indicated that regulatory approval of the Surfaxin® NDA was expected to be received shortly. Because the Company lacked the capacity to manufacture Surfaxin® in compliance with the FDA's current Good Manufacturing Practices, defendants had no reasonable basis to state that the approval of the Surfaxin® NDA was expected to be received shortly.

63. Defendants' disclosures during the Class Period also falsely portrayed the Company's Marketing Approval Application that it submitted to EMEA. As defendant Capetola recently advised analysts, Discovery Labs designed its Phase 3 clinical trial for the use of Surfaxin® to treat RDS to meet FDA standards. Discovery Labs received different scientific advice in its dealings
with EMEA. The Company lacked the resources to follow an alternative protocol, and it therefore submitted the Marketing Approval Authorization based on data from studies that were not designed to meet EMEA’s clinical standards. This material fact was withheld from all of defendants’ statements on the Marketing Authority Application during the Class Period.

The Build-Up to the Company’s NDA Filing.

64. On March 15, 2004, Discovery Labs filed its annual report on Form 10-K for the fiscal year ended December 31, 2003 (“2003 Form 10-K”) with the SEC. The 2003 Form 10-K provided the following overview of the current state of the Company’s product pipeline:

Our technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human lung surfactant. We believe that our surfactant technology provides the opportunity, for the first time, for pulmonary surfactants to be developed into a series of respiratory therapies for critical care and other hospitalized patients where there are few or no approved therapies available. We recently completed two Phase 3 clinical trials of Surfaxin(R), our lead product, for the treatment of Respiratory Distress Syndrome in premature infants and are preparing to file new drug applications with the United States Food and Drug Administration and other regulatory authorities in the rest of the world.

Our Surfactant Replacement Therapy is also in a Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome in adults, as well as in a Phase 3 and Phase 2 clinical trial for the treatment of Meconium Aspiration Syndrome in full-term infants. In addition, we recently completed a successful Phase 1b clinical trial in healthy volunteers and mild asthmatics and are currently preparing to initiate a follow-on Phase 2 clinical trial evaluating the safety, tolerability and efficacy of our humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma.
Presently, we are evaluating the development of other aerosolized formulations of our humanized surfactant to potentially treat premature infants in Neonatal Intensive Care Units in hospitals that are suffering from Respiratory Dysfunction. We are also evaluating aerosolized formulations of our humanized surfactant to potentially treat Acute Lung Injury, chronic obstructive pulmonary disease (often referred to as COPD, which is a chronic condition of the lung that prevents enough oxygen from reaching the blood), rhinitis, sinusitis (infection of the sinuses), sleep apnea and otitis media (inner ear infection).

65. The 2003 10-K also reported on the Company’s efforts to shift from a development stage company to one that had the ability to commercially market Surfacin® once it was formally approved:

We are presently implementing a long-term commercial strategy which includes manufacturing for the production of our humanized surfactant drug products to meet anticipated clinical and commercial needs, and sales and marketing capabilities to execute the launch of Surfacin, if approved, in the U.S. and in Europe.

66. The 2003 10-K stated that the defendants believed that Surfacin® was superior to the existing products:

We believe that our engineered humanized surfactant can be manufactured in sufficient quantities, in more exact and consistent pharmaceutical grade quality, less expensively than the animal-derived surfactants and has no potential to cause adverse immunological responses in young and older adults, all important attributes for our products to potentially meet significant unmet medical needs. In addition, we believe that our engineered humanized surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient’s lungs and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”).
67. The 2003 10-K commented on the relationship with Laureate as follows:

Until recently, our drug product was manufactured at the sterile facilities of our primary contract manufacturer, Akorn, Inc., which was the only manufacturing facility that we had validated to produce clinical material of our humanized surfactant drug product, including Surfaxin. In October 2003, we transferred our manufacturing capabilities from Akorn to a new contract manufacturer, Laureate Pharma, L.P., to install and validate a manufacturing and filling line at their facility for the production of clinical and commercial drug supply in conformance with cGMPs [current Good Manufacturing Practices]. All steps required for production of cGMP material have been completed and we are presently producing Surfaxin for our Phase 2 trial for the treatment of Acute Respiratory Distress Syndrome.

68. The 2003 10-K was reviewed and approved by defendant Capetola, who signed it. The representations concerning the Company’s effort to bring Surfaxin® to market and its relationship with Laureate fell squarely within defendant Schaber’s area of responsibility and were approved or ratified by him.

69. The 2003 10-K was materially false and misleading for the following reasons:

   a. First, the statement that the Company “recently completed two Phase 3 clinical trials of Surfaxin(R), our lead product, for the treatment of Respiratory Distress Syndrome in premature infants and are preparing to file new drug applications with the United States Food and Drug Administration and other regulatory authorities in the rest of the world” was materially false and misleading, as it omitted the material fact that the Phase 3 clinical trials for Surfaxin® to treat RDS had been conducted under protocols discussed with the
FDA. As defendant Capetola recently acknowledged in a conference call with analysts held on July 28, 2006, EMEA had never approved the protocols that Discovery Labs used in the Phase 3 clinical trials.

b. Second, the statement that the Company was in the process of implementing a strategy "to meet anticipated clinical and commercial needs, and sales and marketing capabilities to execute the launch of Surfaxis, if approved, in the U.S. and in Europe" was materially false and misleading because i) defendants had elected to center the manufacture of Surfaxis® at the Totowa Facility, which had a history of problems complying with current Good Manufacturing Practices that they did not disclose to the investing public; and ii) EMEA had never approved the protocols that Discovery Labs used in its Phase 3 clinical trials.

c. Third, the statement that "we believe that our engineered humanized surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life" was materially false and misleading because the Company had not conducted sufficient stability testing under current Good Manufacturing Practices to support it.

d. Fourth, the statement that "[a]ll steps required for production of cGMP material have been completed . . . ," was materially misleading since defendants had elected to center the manufacture of Surfaxis® at a facility with a history of problems complying with current Good
Manufacturing Practices that they did not disclose to the investing public.

Further, as defendant Capetola would reveal during a conference call with analysts held on the afternoon of April 12, 2006, the Totowa Facility had never been used to "commercialize" a product under an NDA before.

70. On March 16, 2004, Discovery Labs issued a press release announcing the results of operations for the fourth quarter of 2003 and the fiscal year. The press release quoted defendant Capetola at length and addressed operational matters that were squarely within the scope of defendant Schaber's responsibilities. The March 16, 2004 release stated as follows:

In the fourth quarter 2003, the Company and Laureate Pharma, L.P. entered into a Technology Transfer And Manufacturing Agreement for the establishment of Surfaxin manufacturing and filling line at their facility for the production of clinical and commercial drug supply. All steps required for the production of material in conformance with current Good Manufacturing Practices (cGMPs) have been completed.

71. This portion of the release was materially misleading since defendants had elected to center the manufacture of Surfaxin® at the Totowa Facility, which had a history of problems in complying with current Good Manufacturing Practices that defendants did not disclose to the investing public.

72. The March 16, 2004 press release also reported that the Company planned to seek approval to market Surfaxin® for RDS:

During 2003, we completed and announced successful results from both a landmark, pivotal Phase 3 clinical trial and a supportive Phase 3 clinical trial of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants. We intend to use the results from these trials to form the basis for a new drug
application (NDA) with the United States Food and Drug Administration as well as for regulatory applications for approval in the rest of the world.

73. This portion of the release was materially misleading since the defendants knew that the Phase 3 data developed did not meet EMEA’s clinical standards, as defendant Capetola recently acknowledged.

74. Two days later, on March 18, 2004, defendant Capetola entered into his second prepaid forward contract, disposing of between 23.02% and 33.83% of his directly owned shares, and receiving over $3.1 million.

75. On March 30, 2004, the Company file a report on Form 8-K, announcing that it had entered into an underwriting agreement with Bear Stearns & Co., Inc. for an offering of 2,200,000 shares of common stock to be issued on or about April 2, 2004. The shares to be sold had been registered pursuant to the registration statement on Form S-3 that the Company filed with the SEC on December 19, 2003.

76. On April 7, 2004, defendant Schaber entered into a prepaid forward contract, disposing of between 82.82% and 99.03% of his directly owned shares and receiving over $2.3 million.

**Discovery Labs Files its NDA for Surfacin® With the FDA.**

77. On April 13, 2004, Discovery Labs filed its NDA with the FDA, seeking approval to market Surfacin® for RDS.

78. On May 6, 2004, the Company issued a press release announcing its results of operations for the first quarter of 2004. The May 6, 2004 release was
appended to a Form 8-K signed by defendant Capetola that was filed with the SEC on May 10, 2004. The release quoted defendant Capetola, and it discussed areas of the Company’s business that were within the scope of defendant Schaber’s duties.

79. The May 6 release commenced with a discussion of the Company’s NDA submitted to the FDA on April 13, 2004. The May 6 release then indicated the following with respect to its plan to seek approval for Surfaxin® in Europe:

The Company is also preparing a Marketing Authorization Application (MAA) to be filed with the European Medicines Evaluation Agency (EMEA) by the middle of 2004 for Surfaxin for the prevention and treatment of RDS. Recently, the Committee for Proprietary Medicinal Products (CPMP) determined that Surfaxin qualified for evaluation through the Centralized Procedure, a more streamlined European regulatory review process that allows for a single application, evaluation and authorization for the entire European Union.

80. The statement that “the Company is also preparing a Marketing Authorization Application to be filed with [EMEA] by the middle of 2004” was materially false and misleading, since defendants knew that the Phase 3 clinical trials that would be used to support this application were prepared under protocols that EMEA had not approved. Further, defendants knew their studies did not provide enough data to satisfy EMEA’s clinical requirements, as recently acknowledged by defendant Capetola.

81. The May 6 release described the Company’s manufacturing operations as follows:
During the first quarter of 2004, the Company completed all steps required for the production of clinical and commercial drug supply of its Surfactant Replacement Therapies (including Surfaxin) in conformance with current Good Manufacturing Practices (cGMPs) at Laureate Pharma, L.P. The Company is presently producing Surfaxin to support its Phase 2 clinical trial for the treatment of ARDS in adults.

82. The description of the Company's manufacturing operations contained in the May 6, 2004 press release was materially misleading because it failed to disclose the material fact that the Totowa Facility had a history of problems in complying with current Good Manufacturing Practices, which defendants did not disclose.

83. On May 7, 2004, Discovery Labs filed its quarterly report on Form 10-Q for the first quarter of 2004 with the SEC. The May 7 10-Q was approved by defendant Capetola and signed by him. It reported on aspects of the Company's business that were central responsibilities of defendant Schaber.

84. The May 7 10-Q reported on the Company's recent NDA filing with the FDA and indicated that the Company was preparing to file a Marketing Approval Application with EMEA without disclosing the material fact that the Phase 3 clinical studies it had conducted on Surfaxin® were not designed to meet EMEA's clinical standards.

85. On June 15, 2004, the Company issued a press release reporting that the FDA had accepted its NDA filing for Surfaxin®. The release quoted defendant Schaber, and it was filed as an exhibit to a Form 8-K signed by defendant Capetola on June 15, 2004. The June 15, 2004 release stated as follows:
Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced that the United States Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) filing for Surfaxin(R) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has granted a Standard Review designation and has established a target date of February 13, 2005 for completion of review of the Surfaxin NDA.

The June 15 release then indicated that the Company's NDA was supported by the Phase 3 clinical trial data it had previously conducted.

86. The June 15 release also described Discovery Labs' plan to seek marketing approval in Europe: "Discovery also is preparing a Marketing Authorization Application (MAA) to be filed with the European Medicines Evaluation Agency (EMEA) in the second half of 2004 for Surfaxin for the prevention and treatment of RDS." The following day, Discovery Labs' common stock closed 14.2% higher.

87. The June 15 press release was materially false and misleading because it failed to disclose that approval of the NDA for Surfaxin® was dependent upon the Company's ability to manufacture the drug in compliance with current Good Manufacturing Practices and that defendants had elected to center the manufacture of Surfaxin® at a facility with a history of problems in complying with current Good Manufacturing Practices. The June 15 press release was also materially false and misleading since it failed to disclose the fact that the Phase 3 clinical trials for Surfaxin® had not been designed to comply with EMEA's clinical standards.
88. On June 30, 2004, Discovery Labs issued a press release indicating that its common stock had received approval to trade on the NASDAQ National Market System, effective as of that date. Prior to that date, the Company’s common stock traded on the NASDAQ Small Cap Market.

89. On July 8, 2004, Discovery Labs issued a press release indicating that it had entered into a Committed Equity Financing Facility Agreement (the “CEFF”) with Kingsbridge Capital Limited (“Kingsbridge”). The release indicated that the facility required Kingsbridge to buy up to 75 million dollars worth of Discovery Labs common stock over a three year period. The July 8 release indicated that the CEFF gave the Company “enormous flexibility” in raising capital. Under the terms of the CEFF, however, there was a threshold price provision, limiting the availability of this facility. If the price for Discovery Labs’ common stock fell below $5.00, Kingsbridge had no obligation to purchase shares under the CEFF.

90. On August 5, 2004, Discovery Labs issued a press release reporting on its results of operations for the second quarter of 2004. The August 5 press release was appended to a Form 8-K signed by defendant Capetola that was filed with the SEC on August 5, 2004. The August 5 release quoted defendant Capetola, and it discussed areas of the Company’s business that were within the scope of defendant Schaber’s duties.

91. In the August 5 release, defendant Capetola said “Discovery now is focusing on preparing for the commercialization of Surfaxon(R) for Respiratory
Distress Syndrome (RDS), if approved.” This statement was materially false and misleading because it failed to disclose the material facts that approval of the NDA for Surfaxin® was dependent upon the Company’s ability to manufacture the drug in compliance with current Good Manufacturing Practices and that defendants had elected to center the manufacture of Surfaxin® at a facility with a history of problems in complying with current Good Manufacturing Practices. Further, as defendant Capetola would reveal in a conference call with analysts on April 12, 2006, the Totowa Facility had never been used to “commercialize” a product under an NDA.

92. The August 5 release commented on the Company’s pending requests for regulatory approval of Surfaxin® as follows:

On June 15, 2004, the United States Food and Drug Administration (FDA) accepted the Company’s NDA filing for Surfaxin for the prevention of RDS in premature infants. The FDA has established a target date of February 13, 2005 for completion of review of the Surfaxin NDA.

The Company is also preparing a Marketing Authorization Application (MAA) to be filed with the European Medicines Evaluation Agency (EMEA) in the second half of 2004 for Surfaxin for the prevention and treatment of RDS. In June, the Committee for Orphan Medicinal Products (COMP) of the EMEA adopted a positive opinion recommending the granting of orphan medicinal product designation for Surfaxin for the prevention and treatment of RDS. In making its assessment the COMP concluded that although satisfactory methods of prevention and treatment of RDS have been authorized in Europe, justifications have been provided that Surfaxin may be of significant benefit to those at risk of developing or affected by the condition.
93. This description of the Company’s pending requests for regulatory approval as set forth in the August 5 release was materially false and misleading. First, the statement “The FDA has established a target date of February 13, 2005 for completion of review of the Surfaxin NDA” was materially false and misleading because it failed to disclose the material facts that approval of the NDA for Surfaxin® was dependent upon the Company’s ability to manufacture the drug in compliance with current Good Manufacturing Practices and that defendants had elected to center the manufacture of Surfaxin® at a facility with a history of problems in complying with current Good Manufacturing Practices. Second, the statement that the Company was “preparing a Marketing Authorization Application (MAA) to be filed with [EMEA] in the second half of 2004” was materially false and misleading since it failed to disclose the material fact that the Phase 3 clinical trials for Surfaxin® had not been designed to comply with EMEA’s clinical standards.

94. On August 9, 2004, the Company filed its quarterly report on Form 10-Q for the second quarter of 2004 with the SEC. The August 9 10-Q was signed by defendant Capetola and it reported on aspects of the Company’s business operations that were defendant Schaber’s primary responsibility. The August 9 10-Q described the Company’s manufacturing capabilities as follows:

Through our contract manufacturer, Laureate Pharma, L.P., we have established a Surfaxin manufacturing line to support the production of clinical and commercial drug supply in conformance with current Good Manufacturing Practices (cGMP). This arrangement provides for the commercial-scale requirements of
Surfaxin for the prevention of RDS in premature infants and our anticipated clinical-scale production requirements of Surfaxin for the treatment of ARDS in adults. Our manufacturing capability has now provided adequate Surfaxin ARDS product to supply all participating clinical sites in order to complete Part B of the Phase 2 study.

This portion of the Form 10-Q was materially false and misleading because it failed to disclose the material facts that the Totowa Facility had a history of problems in complying with current Good Manufacturing Practices and had never been used to "commercialize" a product under an NDA.

95. On August 26, 2004, Discovery Labs filed a registration statement on Form S-3, registering 15,375,000 shares of its common stock to be sold to Kingsbridge under the CEFF.

The Totowa Facility Changes Hands.

96. On October 20, 2004, Safeguard Sciences, Inc. ("Safeguard") and a newly-formed subsidiary entered into an agreement with Laureate and Purdue to purchase all of Laureate's assets, including the Totowa Facility. Safeguard disclosed this acquisition in a Form 8-K filed with the SEC on October 25, 2004. The transaction would close in December.

EMEA Accepts the Company's Marketing Authorization Application.

97. Discovery Labs filed its Marketing Authorization Application with EMEA in October 2004. On October 27, 2004, Discovery Labs issued a press release announcing that EMEA had indicated that its Marketing Authorization Application was complete and that review would commence. The October 27
release quoted defendant Schaber and was appended to a Form 8-K signed by defendant Capetola that was filed on October 28, 2004. The October 27 release stated in relevant part as follows:

DOYLESTOWN, PA -- OCTOBER 27, 2004 -- DISCOVERY LABORATORIES, INC. (NASDAQ: DSCO) today announced that the European Medicines Evaluation Agency (EMEA) has determined that the Marketing Authorization Application (MAA) for Surfaxin(R) for the treatment and prevention of Respiratory Distress Syndrome (RDS) in premature infants has been validated. Validation of the MAA indicates that Discovery's application is complete and that the review process has begun.

Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer of Discovery commented, "We believe the data included in the MAA as well as in our NDA, strongly supports the therapeutic benefit of Surfaxin for infants who suffer from RDS. Based on the positive results from our clinical trials, we are optimistic that Surfaxin will be favorably reviewed by the European regulatory authorities. We look forward to productive interactions with the EMEA and anticipate the review to be completed by the end of 2005. If approved, Surfaxin would represent the world's first engineered version of human lung surfactant."

The MAA submission was supported, in large part, by data from Discovery's two positive Phase 3 RDS clinical trials. The first was a landmark, 1294 patient pivotal study that demonstrated Surfaxin's superiority to Exosurf(R), a non-protein containing synthetic surfactant. Survanta(R), a cow-derived surfactant and the leading surfactant used in the United States, served as a reference arm in the trial. The second trial was a 252 patient supportive study that demonstrated Surfaxin's non-inferiority to Curosurf(R), a pig-derived surfactant and the leading surfactant used in Europe.

98. This October 27 release was materially false and misleading because it emphasized that the Marketing Authority Application was
“supported, in large part, by data from Discovery’s two positive Phase 3 RDS clinical trials,” without disclosing the material fact that the Company’s Phase 3 clinical trials had not been designed to meet EMEA’s clinical standards.

**Discovery Labs Prepares to Market Surfaxin®.**

99. On November 2, 2004, Discovery Labs issued a press release announcing that GE Healthcare Financial Services had increased the amount of its existing capital lease financing facility by up to $6.5 million for a total of $9 million.

100. On November 4, 2004, Discovery Labs issued a press release indicating that it had restructured its existing relationship with Quintiles so that the Company would have full commercialization rights to Surfaxin® in the United States. This release, which was appended to a Form 8-K signed by defendant Capetola that was filed on November 4, 2004, stated in part as follows:

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, “Our proprietary surfactant technology represents a new paradigm that we believe will revolutionize the treatment of respiratory diseases. For the first time, medical practitioners in the NICU can envision surfactant products that are precisely engineered to address various life-threatening respiratory diseases -- and a company capable of fulfilling a commitment to this community.”

In light of defendants’ decision to commit manufacture of Surfaxin® to a facility that had a history of problems complying with current Good Manufacturing Practices, the foregoing statement by Capetola was materially false and
misleading, since the Company faced the material risk that it lacked the manufacturing capability to bring Surfaxin® to market.

101. The Company also issued a press release reporting on the results of its operations for the third quarter of 2004 on November 4, 2006. This November 4 release was appended to a Form 8-K signed by defendant Capetola that was filed on November 4, 2004, and it reported on aspects of the Company’s business that were defendant Schaber’s responsibility. The November 4 release contained the following statement from defendant Capetola:

> “The recent major steps to terminate our collaboration with Quintiles, build our own United States sales and marketing organization, and adjust our pipeline are intended to enhance the commercial and medical value of our Surfactant Replacement Therapies, beginning with the potential launch of Surfaxin which is currently under review by the FDA and the European Medicines Evaluation Agency . . . .”

102. These statements made by defendant Capetola on behalf of the Company were materially false and misleading. First, in light of defendants’ decision to concentrate the manufacture of Surfaxin® at a facility that had a history of problems complying with current Good Manufacturing Practices, the discussion of “potential launch” failed to disclose the material risk that the Company would be unable to manufacture Surfaxin® in compliance with current Good Manufacturing Practices. Second, since the Phase 3 clinical data used to support the Marketing Authorization Application in Europe were not designed to meet EMEA’s clinical standards, the use of the phrase “potential launch” in connection with the Marketing Approval Application was materially misleading.
103. On November 9, 2004, Discovery Labs filed its quarterly report on Form 10-Q for the third quarter of 2004 with the SEC. The November 9 10-Q was signed by defendant Capetola, and it discussed aspects of the Company's business operations that fell squarely within defendant Schaber's responsibilities. In describing the Company, the November 9 10-Q included the following statements:

We have filed a New Drug Application with the FDA and a Marketing Authorization Application with the EMEA for clearance to market Surfaxin, our lead product, for the prevention and treatment of RDS in premature infants. We are also conducting various clinical programs to address ARDS in adults, BPD, a form of chronic lung disease in premature infants, Neonatal Respiratory Failures in premature infants, severe asthma in adults, and MAS in full-term infants.

We are presently implementing a long-term commercial strategy which includes manufacturing for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, and sales and marketing capabilities to execute the launch of Surfaxin, if approved, in the U.S. and Europe.

These statements were materially false and misleading in light of defendants' decision to concentrate the manufacture of Surfaxin® at a facility that had a history of problems complying with current Good Manufacturing Practices, as well as the fact that the Phase 3 clinical trials used to support the Marketing Authorization Application in Europe were not designed to meet EMEA's clinical standards.

104. The November 9 10-Q also described the Company's manufacturing arrangements as follows:
Through our contract manufacturer, Laureate Pharma, L.P., we have established a Surfacin manufacturing line to support the production of clinical and commercial drug supply in conformance with current Good Manufacturing Practices (cGMP). This arrangement provides for the commercial-scale requirements of Surfacin for the prevention of RDS in premature infants and all of our anticipated clinical-scale production requirements including Surfacin for the treatment of ARDS in adults.

This statement was materially false and misleading because it did not disclose the risk that the Company would be unable to manufacture Surfacin® in conformance with current Good Manufacturing Practices, in light of defendants’ decision to utilize the Totowa Facility, which had a history of problems complying with those standards. Defendants also made no mention of the fact that this facility, which was critical to the Company’s ability to bring Surfacin® to market, was undergoing a change in control. The following day, Discovery Labs’ common stock closed 16.15% higher.

105. On or about December 3, 2004, Safeguard’s acquisition of Laureate was concluded. The subsidiary that Safeguard had formed for purposes of the transaction changed its name to Laureate Pharma, Inc. and continued to conduct Laureate’s business, including operation of the Totowa Facility. Safeguard disclosed the completion of this acquisition in a Form 8-K filed with the SEC on December 7, 2004.

106. On December 7, 2004, Discovery Labs issued a press release which disclosed that it had restructured its existing relationship with Esteve. The release indicated that in return for issuance of common stock and certain
payments to Esteve, "Discovery regained full commercialization rights for its
SRT products including Surfaxin, for RDS and ARDS in Europe (excluding
Southern Europe which is retained by Esteve, as mentioned below), Central
America, and South America." Discovery Labs issued 500,000 shares of common
stock to Esteve at no cost to Esteve in connection with this transaction.

107. The same day, Discovery Labs issued a press release announcing
that it had "encouraging preliminary data from its Surfaxin® Phase 2 clinical trial
for the treatment of Acute Respiratory Distress Syndrome (ARDS) in adults.”

108. According to a Form 8-K filed on December 29, 2004, on December
10, 2004, Discovery Labs notified Kingsbridge of its intention to conduct a
financing of up to $12 million under the CEFF. The pricing of shares issued
pursuant to the CEFF was set by a formula that focused upon the price of the
Company’s common stock over a 15 day trading period, subject to certain
discounts. Kingsbridge was only obligated to purchase shares to the extent that
the market price for Discovery Labs common stock exceeded a minimum price
on particular days during the 15 day trading period. The December 29 8-K
described the closing of this transaction as follows:

As of December 29, 2004, twelve trading days of the Financing
Period had transpired and the Company issued 901,742 shares (the
"Shares") to Kingsbridge (with 489,249 shares settled on December
22, 2004 and 412,493 shares settled on December 29, 2004) for
aggregate cash proceeds to the Company of $7.2 million.
The FDA Inspects the Totowa Facility.

109. As part of its review of the Surfaxin® NDA, the FDA inspected the Totowa Facility where Laureate manufactured Surfaxin®. While the exact dates when the inspection was conducted are not presently known, in January of 2005, the FDA issued a Form 483 to Laureate Pharma, Inc. (the Safeguard affiliate that had assumed control of the facility), reporting on various problems in complying with current Good Manufacturing Practices at the Totowa Facility.

110. Discovery Labs first disclosed the FDA inspection and the Form 483 on February 1, 2005, when it issued a press release providing an update on the status of its NDA for Surfaxin®. The press release, which was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, stated as follows:

Discovery Laboratories, Inc. (Nasdaq: DSCO) is providing an update regarding key pre-approval inspection activities conducted by the U.S. Food and Drug Administration (FDA) in connection with the review of Discovery's New Drug Application (NDA) for Surfaxin® for the prevention of Respiratory Distress Syndrome in premature infants. The reporting of these inspection activities and the review of the Surfaxin NDA are the subject of a PDUFA letter that the Company anticipates receiving from the FDA on or about February 13, 2005.

The FDA has conducted pre-approval inspections of the NDA's major components which include preclinical, clinical, chemistry, and manufacturing. To date, the results of the FDA's pre-approval inspections of Discovery's clinical data and clinical study sites have been extremely favorable. The Company believes that the clinical data is sufficient for approval and does not anticipate the need for additional trials to support approval.
With respect to manufacturing, the FDA recently issued a Form 483 to Laureate Pharma, Inc. (Laureate), Discovery's contract manufacturer of Surfaxin, citing inspection observations relating to compliance with current Good Manufacturing Practices (cGMPs) and other processes to be used for commercial production of the product. In response, Laureate and Discovery submitted a cGMP Action Plan on January 31, 2005 outlining measures intended to address the FDA's observations. The corrective actions outlined in the Action Plan are anticipated to be completed by July 2005. The commercial launch of Surfaxin, if approved, is now anticipated to occur in the fourth quarter of 2005.

111. The Company's release indicated that the issues identified by the FDA were readily remediable:

The general theme of the inspection observations relates to basic quality controls, process assurances and documentation requirements that support the commercial production process. The Company believes that the Form 483 inspection observations are highly correctable in a reasonable period of time and do not relate to any clinical material produced to date. Based on the Form 483 issued to Laureate, Discovery now anticipates receiving a PDUFA letter constituting a Class 2 response, which will allow the FDA up to six months to review Discovery's NDA response and conduct a reinspection of Laureate's Totowa facility.

The FDA's Form 483 observations should be considered in light of the following:

- The raw materials contained in Surfaxin are purchased from third parties. These vendors have been inspected by the FDA with no significant observations noted to date.

- Discovery employs its own manufacturing equipment with its proprietary process on the premises of Laureate in Totowa, New Jersey. There are no fundamental flaws with the general manufacturing process of Surfaxin.

- There are no safety issues with the Surfaxin material that has been manufactured and shipped from Laureate to Discovery's clinical trial sites for use in its ongoing trials.
Discovery and Laureate have formed an Executive Steering Committee, consisting of Discovery's Chief Operating Officer [defendant Schaber], Laureate's President, and the Chairman of Laureate's Board of Directors, to oversee the correction of these observations in the shortest possible time.

112. In fact, as defendants would later disclose, the manufacturing process for Surfaxin® was highly complex, as the product had multiple active ingredients, a factor that differentiated it from most other drugs. The defendants, however, decided to portray the problems outlined by the FDA following its inspection of the Totowa Facility as easily remediable.

113. The price of Discovery Labs' common stock dropped sharply in response to the February 1 release. The closing price for the Company's common stock was 22.07% lower on February 1, 2005 than it was on January 31, 2005.

Discovery Labs Receives an "Approvable Letter" from the FDA.

114. On February 14, 2005, Discovery Labs announced that it had received an "Approvable Letter" for Surfaxin®, stating as follows:

The Approvable Letter is an official notification that the FDA is prepared to approve the Surfaxin New Drug Application and contains conditions that the applicant must meet prior to obtaining final U.S. marketing approval. The conditions that Discovery must meet primarily involve finalizing labeling and correcting previously reported manufacturing issues. Most notably, the FDA is not requiring additional preclinical or clinical trials for final approval. The Company anticipates potential approval and commercial launch of Surfaxin to occur in the fourth quarter of 2005 or first quarter of 2006.

The press release quoted defendant Capetola as follows: “This is a momentous occasion for Discovery Labs and its prospective patients . . . .” This February 14
press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it reported on aspects of the Company’s business that were defendant Schaber’s responsibility.

115. The FDA defines an “Approvable Letter” as an indication that a drug could be approved, but only if certain conditions are met:

Approvable letter means a written communication to an applicant from FDA stating that the agency will approve the application or abbreviated application if specific additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of any part of an application or abbreviated application and does not permit marketing of the drug that is the subject of the application or abbreviated application.

21 C.F.R. § 314.3.

116. The price of Discovery Labs common stock rose when the “Approvable Letter” was announced, closing 10.88% higher on February 14, 2005.

117. Shortly after that announcement, on February 17, 2005, the Company filed an amendment to the registration statement that it had filed on December 19, 2003, registering additional shares. The Company issued a press release on February 18, 2005, indicating that it had obtained commitments for the sale of approximately 4.6 million shares of common stock to a group of institutional investors in a registered direct offering that raised $26.5 million, and it filed a prospectus for that offering on the same day. The Company issued a second release on February 18, 2005, disclosing that it had received an additional
commitment to purchase 450,000 shares for approximately $2.6 million of its common stock as part of this registered direct offering.

118. On March 16, 2005, Discovery Labs filed its Annual Report on Form 10-K for 2004 (the "2004 10-K") with the SEC; the 2004 Form 10-K was signed by defendant Capetola, and it reported on aspects of the Company's business that were defendant Schaber's responsibility. The Company's Form 10-K for 2004 described the prospects for Surfaxin® as follows:

Presently, the FDA has approved surfactants as replacement therapy only for RDS in premature infants, a condition in which infants are born too soon and thus have an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from pig and cow lungs. Although they are clinically effective, they have drawbacks and cannot readily be scaled or developed to treat broader populations for RDS in premature infants and other respiratory diseases. There is presently only one approved synthetic surfactant available, however, this product does not contain surfactant proteins, is not widely used and is not actively marketed by its manufacturer.

Animal-derived surfactant products are prepared using a chemical extraction process from minced cow and pig lung. Because of the animal-sourced materials and the chemical extraction processes, there can potentially be significant variation in production lots and, consequently, product quality specifications must be broad. In addition, the protein levels of these animal-derived surfactants are inherently lower than the protein levels of native human surfactant. The production costs of these animal-derived surfactants are high, relative to other analogous pharmaceutical products, generation of large quantities is severely limited, and these products cannot readily be reformulated for aerosol delivery to the lungs.

Our precision-engineered surfactant product candidates, including Surfaxin, are engineered versions of natural human lung surfactant and contain a precision-engineered peptide, sinapultide. Sinapultide is a 21 amino acid protein-like substance that is
designed to closely mimic the essential attributes of human surfactant protein B (SP-B), the surfactant protein that is most important for the proper functioning of the respiratory system. Our products have the ability to be precisely formulated, either as a liquid instillate, aerosolized liquid or dry powder, to address various medical indications.

We believe that our precision-engineered surfactant can be manufactured in sufficient quantities, in more exact and consistent pharmaceutical grade quality, less expensively than the animal-derived surfactants and has no potential to cause adverse immunological responses in young and older adults, all important attributes for our products to potentially fulfill significant unmet medical needs. In addition, we believe that our precision-engineered surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient’s lungs and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”).

119. This section of the 2004 10-K was materially false and misleading. First, the statement that “We believe that our precision-engineered surfactant can be manufactured in sufficient quantities, in more exact and consistent pharmaceutical grade quality, less expensively than the animal-derived surfactants” was false and misleading because the defendants had not yet established a facility that was capable of producing Surfaxin® that could consistently pass stability testing consistent with current Good Manufacturing Practices. Second, the statement that “we believe that our precision-engineered surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life” was materially false and
misleading because the Company had not conducted sufficient stability testing under current Good Manufacturing Practices to support it.

120. The 2004 10-K reported on the status of the Surfaxin® NDA as follows:

In February 2005, we received an Approvable Letter from the U.S. Food and Drug Administration (FDA) for clearance to market Surfaxin® (lucinactant), our lead product, for the prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants. The Approvable Letter is an official notification that the FDA is prepared to approve the Surfaxin New Drug Application and contains conditions that the applicant must meet prior to obtaining final U.S. marketing approval. The conditions that we must meet primarily involve finalizing labeling and correcting previously reported manufacturing issues. Most notably, the FDA is not requiring additional preclinical or clinical trials for final approval. Based on the nature of the observations contained in the Approvable Letter, we currently anticipate that we will respond to the FDA with a “Class 2” response. A “Class 2” response allows the FDA up to six months following the completion of the labeling and manufacturing issues outlined in the Approvable Letter.

With respect to the manufacturing issues mentioned above, in January 2005, the FDA issued an inspection report (Form FDA-483) to Laureate, our contract manufacturer of Surfaxin, citing certain observations concerning Laureate’s compliance with current Good Manufacturing Practices (cGMPs) in connection with its review of our NDA for Surfaxin for RDS. The general focus of the inspection observations relates to basic quality controls, process assurances and documentation requirements to support the commercial production process. In response, a cGMP Action Plan was submitted to the FDA on January 31, 2005, outlining corrective measures anticipated to be completed by July 2005. Assuming the adequacy of such corrective actions and the approval of marketing clearance for Surfaxin, we anticipate that the potential approval and commercial launch of Surfaxin for the United States will occur in the first quarter of 2006. Our other clinical programs currently in progress are not affected by this inspection report and remain on track. However, if the inspection observations noted in the Form
483 are not resolved in the time period stated above, a delay may occur in these programs.

121. This portion of the 2004 10-K was materially false and misleading. The 2004 10-K indicated that the Company and Laureate Pharma, Inc. had concluded a cGMP Action Plan and that defendants anticipated “potential approval and commercial launch” for Surfaxin® in early 2006. These statements were materially false and misleading because defendants had committed the manufacture of Surfaxin® to a facility with a history of problems in complying with current Good Manufacturing Practices, and Discovery Labs lacked sufficient personnel with relevant expertise to remediate the Totowa Facility. Ultimately, Discovery Labs would buy the facility and bring in new manufacturing and quality control experts from outside the Company in a belated effort to bring the Totowa Facility into compliance with current Good Marketing Practices.

122. The 2004 10-K reported on the status of the Company’s Marketing Authorization Application, as follows:

In October 2004, the European Medicines Evaluation Agency validated our Marketing Authorization Application that we had filed previously for clearance to market Surfaxin for the same indication in Europe. This validation indicated that the Marketing Authorization Application was complete and that the review process had begun. We anticipate the potential approval of Surfaxin for Europe will occur in the first quarter of 2006.

This statement was materially false and misleading, as it failed to disclose that the Phase 3 clinical trials used in connection with the Marketing Authorization
Application to the EMEA had not been designed to meet EMEA’s clinical standards.

123. On April 27, 2005, Discovery Labs issued a press release reporting on its results of operations for the first quarter of 2005. This April 27 press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it discussed areas of the Company’s business that were defendant Schaber’s responsibility. The April 27 release quoted defendant Capetola as follows:

With regards to the Approvable Letter we received from the FDA for Surfaxin, we are working diligently with our drug product contract manufacturer to address the manufacturing matters raised by the FDA. Due to our collaborative efforts, we remain on schedule to submit a Complete Response Letter to the FDA by July 2005. Our organization is committed to the anticipated commercial launch of our first precision-engineered surfactant product in the first quarter of 2006.

124. The foregoing statements were false and misleading, as the Company lacked sufficient personnel with relevant expertise to remediate the Totowa Facility.

125. The April 27 press release also discussed the fact that the Company had filed a Marketing Authorization Application for Surfaxon® to treat RDS in Europe, without disclosing the material fact that the Company’s Phase 3 clinical trials had not been designed to meet EMEA’s clinical standards.

126. On May 4, 2005, the Company filed its Form 10-Q for the first quarter of 2005 with the SEC. This filing was signed by defendant Capetola, and
it reported on aspects of the Company's business that were defendant Schaber's responsibility. The May 4 10-Q described the status of the Surfaxin® NDA as follows:

We have received an Approvable Letter from the U.S. FDA for Surfaxin® (lucinactant), our lead product, for the prevention of RDS in premature infants, and have filed a Marketing Authorization Application (MAA) with the European Medical Evaluation Agency (EMEA) for clearance to market Surfaxin in Europe. We anticipate potential approval and commercial launch of Surfaxin in the United States and potential EMEA approval to occur in the first quarter of 2006.

This statement was materially false and misleading, as it failed to disclose that the Phase 3 clinical trials used in connection with the Marketing Authorization Application to the EMEA had not been designed to meet EMEA's clinical standards.

127. The May 4 10-Q also described the Company's manufacturing operations as follows:

We anticipate that our manufacturing capabilities through Laureate, upon successful completion and implementation of its cGMP Action Plan dated January 31, 2005, should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the prevention of RDS in premature infants and all of our anticipated clinical-scale production requirements including Surfaxin for the treatment of ARDS in adults.

128. This portion of the May 4 10-Q was materially false and misleading because the defendants had committed the manufacture of Surfaxin® to a facility with a history of problems in complying with current Good Manufacturing
Practices that they did not disclose, and defendants lacked sufficient personnel with relevant expertise to remediate the Totowa Facility.

**Discovery Labs Manufactures Process Validation Batches.**

129. As defendants would later disclose, between June and August of 2005, Discovery Labs was in the process of preparing process validation batches at the Totowa Facility to support its NDA. Shortly after the last of these process validation batches was produced, the Company elected to make a draw under the CEFF to raise $17 million that would be used to acquire manufacturing facilities. Although this transaction was concluded in September 2005, it was first disclosed in November 2005. In the interim, defendants’ disclosures continued to assure investors that the problems at the Totowa Facility were under control. Further, while the prior draw on the CEFF was the subject of an 8-K filing, this draw was not.

**Discovery Labs Responds to the “Approvable Letter.”**

130. On July 29, 2005, the Company submitted a response to the FDA’s “Approvable Letter.” That same day, it announced this to the public as follows:

Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced that it has submitted its response to the Approvable Letter received from the U.S. Food and Drug Administration (FDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The Company believes that the response addresses the comments noted in the Approvable Letter by providing the FDA with the information necessary to complete its review of the Surfaxin New Drug Application (NDA) within six months.
In February 2005, the FDA issued an Approvable Letter indicating that it is prepared to approve the NDA when issues noted in the letter are adequately addressed. Most importantly, the FDA is not requiring additional preclinical or clinical studies. The Approvable Letter addressed certain labeling, chemistry, and manufacturing issues. With respect to Discovery’s contract manufacturer, Laureate Pharma, Inc. (Laureate), the FDA previously issued a Form 483, citing inspectional observations related to compliance with current Good Manufacturing Practices (cGMPs) and other processes to be used for commercial production of the product. The general theme of the observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process.

Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer of Discovery commented, “Discovery and Laureate have worked aggressively to implement improved quality systems and documentation controls. We believe these efforts support our response to the FDA Approvable Letter and prepare us for the FDA’s reinspection of Laureate’s Totowa facility. We are confident that these actions bring Surfaxin, the first precision-engineered Surfactant Replacement Therapy, closer to the neonatal community as we anticipate approval and commercial launch in the first quarter of 2006.”

131. This July 29, 2005 press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it addressed aspects of the Company’s business that were defendant Schaber’s responsibility. While the press release indicated that the defendants were confident that they had addressed the problems at the Totowa Facility, that was not the case. They would shortly make a $17 million draw under the CEFF to acquire manufacturing facilities. In a little over three months, defendants would announce that they had been working to obtain direct control over the Totowa Facility and “were making progress towards achieving this goal.” By the end of
2005, they would announce that they had concluded negotiations for the outright purchase of the Totowa Facility and signed a definitive agreement.

132. On August 2, 2005, the Company issued a press release reporting on its results for the second quarter of 2005. That release quoted defendant Capetola as follows:

With the recent submission of our Response to the FDA Approvable Letter for Surfacin, we are prepared for the FDA to complete its review of our NDA within the next six months. We believe that we are well positioned as a company based on the potential U.S. launch and European approval of Surfacin in the first quarter of 2006, collaborative commercialization opportunities in Europe and Japan, potential financial resources of approximately $110 million and a broad pipeline centered upon our SRT technology that, to date, has achieved significant milestones.

This statement was materially false and misleading, as it failed to disclose that the Phase 3 clinical trials used in connection with the Marketing Authorization Application to EMEA had not been designed to meet EMEA’s clinical standards.

133. This August 2, 2005 press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it discussed aspects of the Company’s business that were defendant Schaber’s responsibility.

134. On August 5, 2005, Discovery Labs filed its Form 10-Q for the second quarter of 2005 with the SEC; this filing was signed by defendant Capetola, and it discussed aspects of the Company’s business that were defendant Schaber’s responsibility. The August 5 10-Q included the following statement:
We have received an Approvable Letter from the FDA for Surfascin® (lucinactant), our lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and we have filed a Marketing Authorization Application (MAA) with the European Medicines Evaluation Agency (EMEA) for clearance to market Surfascin in Europe.

This statement was materially false and misleading, as it failed to disclose that the Phase 3 clinical data used in connection with the Marketing Authorization Application to the EMEA had not been designed to meet EMEA's clinical standards.

135. The August 5 10-Q described the status of the NDA for Surfascin® as follows:

In January 2005, the FDA issued an inspection report (FDA Form-483) to Laureate citing certain observations concerning Laureate's compliance with current Good Manufacturing Practices (cGMPs) in connection with the FDA's review of our NDA for Surfascin for the prevention of RDS in premature infants. The general focus of the inspection observations related to basic quality controls, process assurances and documentation requirements to support the commercial production process. On July 29, 2005, we submitted a response to the Approvable Letter to the FDA. We believe that the quality systems and documentation control enhancements that we have implemented jointly with Laureate to support this response prepare us for the FDA's reinspection of Laureate's Totowa facility. Assuming the adequacy of such corrective actions and the approval of the NDA, we anticipate that the commercial launch of Surfascin will occur in the first quarter of 2006.

136. The statement "We believe that the quality systems and documentation control enhancements that we have implemented jointly with Laureate to support this response prepare us for the FDA's reinspection of Laureate's Totowa facility" was materially false and misleading because
defendants were not in fact satisfied with the remediation efforts at the Totowa Facility and were working to obtain direct control over it.

**The FDA Addresses the Company’s Response to the “Approvable Letter.”**

137. While the Company considered its response to the FDA’s “Approvable Letter” to be complete, the FDA did not. On August 15, 2005, the Company issued a press release indicating that it had received an informal communication indicating that the FDA did not consider Discovery Labs’ response to the Approvable Letter to be complete. The release quoted defendant Capetola as follows:

The response we recently submitted to the FDA’s Approvable Letter for Surfaxin was encyclopedic and comprehensive. Based upon the thoroughness of our Response Letter, we are optimistic that the FDA’s issues will center on a few select items that are capable of being addressed in an as timely and efficient manner as possible. Of course, we will have greater clarity on these matters once we have received and fully assessed the FDA’s official communication which we expect later this week. At that time, we anticipate holding a conference call to communicate more detailed information with our shareholders. We believe that our relationship with the FDA has always been collaborative and very productive. We anticipate prompt discussions with the FDA and moving forward to finalize a complete response as quickly as possible.

138. This August 15, 2005 press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it discussed aspects of the Company’s business that were defendant Schaber’s responsibility. In response to this news, the Company’s common stock closed 9.54% lower on August 15, 2005.
139. Shortly after the August 15 release was issued, the Company received the FDA's formal written comments. On August 19, 2005, the Company issued a press release discussing the formal FDA comments that it received on Discovery Labs' response to the Approvable Letter:

Discovery Laboratories, Inc. (Nasdaq: DSCO) has received formal written notification from the U.S. Food and Drug Administration (FDA), following its review of the Company's previously submitted Response Letter, outlining select items that need to be addressed in order for the FDA to deem the response complete. The Company's Response Letter to the FDA's Approvable Letter for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants was previously submitted on July 29, 2005.

In its written notification, the FDA outlined twelve items, centered on chemistry and manufacturing, that require further clarification or additional information to support the Company's comprehensive response. These items are not related to the quality of the Surfaxin clinical trials or their results. Additionally, the items do not raise any new issues related to the Company's contract drug product manufacturer, Laureate Pharma, Inc. The Company is in the process of addressing these items and anticipates submitting its response to the FDA in October 2005. The approval of Surfaxin is now anticipated in April 2006 with commercial launch to occur in the second quarter of 2006.

140. This August 19, 2005 press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it discussed aspects of the Company's business that were defendant Schaber's responsibility.

141. In September 2005, the exact date not having been publicly disclosed, the Company conducted a financing under the CEFF that raised $17.0 million from the issuance of 3,012,055 shares of common stock. As the defendants
would disclose in November, these funds were earmarked to buy the troubled
Totowa Facility.

142. On October 11, 2005, Discovery Labs filed a shelf registration for
the potential future issuance of debt and equity securities of up to $100 million.
The same day, the Company issued a press release indicating that it had no
immediate plans to sell securities, but the filing was “intended to enable
Discovery to react to market opportunities as they arise.”

143. On October 21, 2005, Discovery Labs issued the following press
release:

Discovery Laboratories, Inc. (Nasdaq: DSCO), has been informed
today by the U.S. Food and Drug Administration (FDA) that the
FDA has accepted Discovery’s resubmission of October 5, 2005 as a
complete response to the Approvable Letter for Surfaxin®, for the
prevention of Respiratory Distress Syndrome (RDS) in premature
infants. The FDA has established April 2006 as its target to
complete its review of the Surfaxin New Drug Application (NDA).

Robert J. Capetola, Ph.D., President and Chief Executive Officer of
Discovery, commented, “With the acceptance of our response to the
Surfaxin Approvable Letter, the FDA six month review process has
begun as of October 5, 2005, the date of our resubmission.
Discovery will work diligently with the FDA during this review,
which will include the reinspection of our Surfaxin contract
manufacturing facility, Laureate Pharma in Totowa, New Jersey.
We anticipate that Surfaxin, the first precision-engineered
Surfactant Replacement Therapy, will be available to the neonatal
medical community in the second quarter of 2006.”

144. This October 21, 2005 press release was filed with the SEC as an
exhibit to a current report on Form 8-K signed by defendant Capetola, and it
discussed aspects of the Company’s business that were defendant Schaber’s
responsibility. The price for Discovery Labs’ common stock rose in response to the news: the Company’s common stock closed 10.89% higher on October 21, 2005.

145. On October 27, 2005, the Company filed a current report on Form 8-K with the SEC, indicating that it had entered into an agreement to sell 650,000 shares of its common stock to Esteve, at a price per share of $6.88, for an aggregate purchase price of $4,472,000 under the amended registration statement filed by the Company in February of 2005.

**Discovery Labs Reveals its Intent to Assume Control of Manufacturing.**

146. On November 3, 2005, Discovery Labs issued a press release concerning its results of operations for the third quarter of 2005. This November 3 press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it addressed aspects of the Company’s business that were defendant Schaber’s responsibility.

147. The November 3 release quoted defendant Capetola as follows: “Surfaxin, our lead product with an FDA Approvable Letter, is now under a six month review by the FDA that began on October 5, 2005. We are preparing our organization for the potential approval of Surfaxin in April 2006, followed by the commercial launch in the second quarter of 2006.”

148. Although the Company had repeatedly assured investors that it was satisfied with remediation efforts it had made with Laureate Pharma, Inc. to address the FDA’s Form 483 inspection report, defendant Capetola now
indicated that “it is strategically important to manage our own manufacturing and commercial operations and we are making steady progress towards achieving this goal.” The release indicated that this acquisition would be funded through the proceeds of the CEFF transaction that had closed in September 2005.

149. The same day, in a telephone conference with securities analysts, defendant Capetola stated that “we have completed remediation related to that Form 43 (sic) that we showed—we talked about with you in the first quarter of 2005 and we have completed our process validation rounds.”

150. On November 9, 2005, Discovery Labs filed its Form 10-Q for the third quarter of 2005 with the SEC. This filing was signed by defendant Capetola, and it addressed aspects of the Company’s business that were defendant Schaber’s responsibility. The November 9 10-Q contained the following statement: “Our lead product, Surfaxin® (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) and is under review for approval in Europe by the European Medical Evaluation Agency (EMEA),” without revealing the material fact that the Phase 3 clinical trials that the Company had conducted were not designed to meet EMEA’s clinical criteria.

151. The November 9 10-Q described the status of the NDA for Surfaxin® as follows:
Our previously submitted responses to the Approvable Letter have been accepted by the FDA as a complete response as of October 5, 2005. This date also marks the start of the six month review period during which the FDA expects to complete its review of our NDA for Surfaxin for the prevention of RDS in premature infants. We believe that the quality systems and documentation control enhancements that we have implemented jointly with Laureate to support our response to the FDA prepare us for the FDA’s reinspection of Laureate’s Totowa facility within the six month review cycle. Some pre-approval activities related to our Surfaxin manufacturing process, including process validation, have been completed, while certain reinspection activities are ongoing. Assuming that such corrective actions are adequate, we anticipate that our NDA will be approved in April 2006 and that the potential commercial launch of Surfaxin will occur in the second quarter of 2006.

152. On December 11, 2005, Discovery Labs announced that it had entered into a strategic alliance with the Chrysalis Technologies unit of Phillip Morris USA Inc. to “develop and commercialize aerosolized surfactant replacement therapies (aSRT) to address a broad range of serious respiratory conditions.”

153. Three days later, on December 14, 2005, the Company announced that it had received commitments from institutional investors to purchase approximately 3.0 million shares of its common stock in a transaction expected to close December 19, 2005. Thereafter, on December 20, 2005, Discovery Labs issued a press release indicating that it had finalized this transaction, selling a total of 3,030,304 shares of common stock to select institutional investors at $6.60 per share, resulting in gross proceeds of $20.0 million.
Discovery Labs Buys The Totowa Facility.

154. Although the defendants had repeatedly stated that they were satisfied that the problems identified by the FDA in its inspection of the Totowa Facility had been resolved, Discovery Labs decided to buy the facility and install new manufacturing and quality control personnel.

155. Specifically, on December 28, 2005, Discovery Labs issued a press release indicating that it had entered into an agreement with Laureate Pharma, Inc. to acquire the Totowa Facility where Surfaxin® was manufactured. The release indicated that the acquisition was "intended to provide Discovery with operational control and improved economics for the potential commercial and clinical production of Discovery’s lead product, Surfaxin®, and its pipeline of precision-engineered Surfactant Replacement Therapy (SRT) products.” This December 28, 2005 press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it addressed aspects of the Company’s business that were defendant Schaber’s responsibility.

156. The December 28 release announcing the acquisition of the Totowa Facility summarized the terms of the transaction as follows:

Effective December 27, 2005, Discovery and Laureate Pharma, Inc. entered into an asset purchase agreement that provides for Discovery’s purchase of Laureate’s Totowa operations. Certain key terms and items related to the transaction include:

- Discovery will pay Laureate $16 million in cash at closing.
• The approximately 21,000 square foot facility is currently leased by Laureate, and Discovery will receive an assignment of the existing lease, with a lease term expiring in December 2014. The lease is subject to customary terms and conditions and contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and payment of significant early termination amounts to Discovery.

• At closing, Discovery will employ a majority of the approximately 25 personnel that are qualified in sterile pharmaceutical manufacturing and currently employed at the operations.

• Related to the payment of the purchase price and other costs and expenses associated with the transaction, Discovery anticipates taking an estimated $17 million charge to research and development expense for the fourth quarter of 2005.

• To provide for additional formulation and aerosol development capabilities related to its future SRT pipeline plans, Discovery intends in 2006 to make additional investments of approximately $5 million in the manufacturing operations....

157. The same day, the Company announced that it was hiring two new executives: Gerald Katzer, who was named Senior Vice President Manufacturing Operations, and Gerald Orehotsky, who was named Vice President Quality Operations. The release indicated that Orehotsky would “be responsible for the development and enhancement of GMP [Good Manufacturing Practices], quality processes and systems to promote, facilitate and assure sustainable compliance with all regulatory standards.” These two new executives were to report to
defendant Schaber, who had previously been responsible for the oversight of Laureate’s performance of these functions.

158. On February 23, 2006, Discovery Labs issued a press release, announcing its results of operations for the fourth quarter of 2005 and the fiscal year. The release quoted defendant Capitola as follows: “This past quarter, we believe we have significantly strengthened our Company, both financially and operationally in preparation for the potential FDA approval in April 2006 and U.S. commercial launch in the second quarter of 2006 of our lead product, Surfaxis®.” This February 23, 2006 press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it reported on aspects of the Company’s business that were defendant Schaber’s responsibility.

159. On March 16, 2006, the Company filed its Annual Report on Form 10-K for 2005 (the “2005 10-K”) with the SEC, which was signed by defendant Capetola and which reported on aspects of the Company’s business that were defendant Schaber’s responsibility. The 2005 10-K indicated that the FDA had established April 2006 as the target date for the completion of review of the Surfaxis® NDA. Discovery Labs summarized the status of the NDA as follows:

   In February 2005, we received an Approvable Letter from the FDA for clearance to market Surfaxis, our lead product, for the prevention and treatment of RDS in premature infants. As part of the review of the Surfaxis NDA, the FDA, in January 2005, issued an inspection report (Form FDA-483) to Laureate, at that time our contract manufacturer of Surfaxis, citing certain observations concerning Laureate’s compliance with cGMPs [current Good
Manufacturing Practices. To address the inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA’s regulatory requirements for approval of Surfaxon.

Our previously submitted responses to the Approvable Letter were accepted by the FDA as complete responses as of October 5, 2005. Assuming that the corrective actions made to the Surfaxon manufacturing operations in Totowa, NJ are adequate, we anticipate that our NDA will be approved in April 2006 and that the U.S. commercial launch of Surfaxon will occur late in the second quarter of 2006.

160. Shortly after the Company filed the 2005 10-K, the FDA commenced a three week re-inspection of the Totowa Facility that would conclude on April 7, 2006.

Surfaxin® Is Not Approved.

161. Because the FDA had deemed Discovery Labs’ response to the “Approvable Letter” to be complete as of October 5, 2005 and indicated that the Surfaxon® NDA for RDS would receive a class two review, the review process was due to conclude on April 5, 2006, six months from the date that the response to the “Approvable Letter” was deemed complete. All of the defendants’ disclosures in the interim had displayed a buoyant optimism that Surfaxon® would be approved, and that Discovery Labs would shift from a development stage company to an operating company with a unique product for sale. This would have represented a huge shift in the Company’s fortunes, as it would switch from burning cash to earning it.
162. But Surfaxin® was not approved. Instead, on April 5, 2006, Discovery Labs issued a press release indicating that it had received a second "Approvable Letter" for Surfaxin®, which it described as follows:

The Approvable Letter is an official notification from the FDA and contains conditions that must be satisfied by Discovery prior to obtaining final U.S. marketing approval. Specifically, the FDA is requesting certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. Consistent with previous review, the FDA does not have any clinical or statistical comments. Discovery is in the process of arranging a meeting with the FDA regarding conditions for final approval. The Company anticipates that this meeting will clarify timelines with respect to its response to the FDA.

163. This April 5, 2006 press release was filed with the SEC as an exhibit to a current report on Form 8-K signed by defendant Capetola, and it reported on aspects of the Company's business that were defendant Schaber's responsibility. The price for the Company's common stock plummeted in response to this disclosure, closing 29.16% lower on April 5, 2006.

164. On April 12, 2006, the Company held a conference call with analysts. The Company thereafter summarized the content of the conference call in a Form 8-K signed by defendant Capetola that was filed on April 18, 2006. The April 18 Form 8-K reported on the Company's Marketing Authorization Application in Europe as follows:

European Medicines Evaluation Agency (EMEA) Inspection Update
In February 2006, the Medicines and Health Products Regulatory Agency (MHRA) conducted an on-site inspection of the Company’s manufacturing facility on behalf of the EMEA. Such on-site inspection is required by the EMEA before the grant of a Marketing Authorization. EMEA regulatory guidelines provide that manufacturing facility inspectional observations are classified into three categories: “critical,” “major” and “other.” The February 2006 inspectional observations report contained observations categorized only as “other.”

The Company responded in writing to all of the EMEA inspectional observations within 14 days of the conclusion of the inspection. The Company has not received any objections, comments or questions from the EMEA to its responses to date. Since the timeline, per EMEA guidance, for providing any such comments has expired, the Company considers the EMEA site inspection process satisfactorily completed.

165. The April 18 Form 8-K reported on the status of the Surfaxin® NDA as follows:

Food and Drug Administration (FDA) Inspection Update

The FDA concluded a three-week re-inspection of the Company’s manufacturing facility on April 7, 2006. The FDA had previously conducted a pre-approval inspection of the facility in January 2005, at which time the FDA had certain observations concerning the facility’s compliance with current Good Manufacturing Practices (cGMPs). The inspection observations at that time were associated primarily with basic quality controls, process assurances and documentation requirements to support the commercial production process, to which the Company responded by implementing an extensive cGMP corrective action plan, which also included the revalidation of the media and process validation runs.

The focus of the FDA re-inspection centered on the corrective actions to the Form FDA-483 issued in January 2005, as well as related manufacturing and quality operations, systems and controls. The FDA issued an inspectional observations report (Form FDA-483) citing certain observations related predominantly to the clarification of procedures, documentation and preventative maintenance. The report did not note a requirement of re-
inspection of the facility. The Company expects to submit its response to a majority of the Form FDA-483 items within the next two weeks.

One item noted on the inspection report relates to certain drug product specification issues cited in the second Approvable Letter the Company received on April 5, 2006. The Company plans on responding to this inspectional item in its complete response to the second Approvable Letter. The Company believes that its satisfactory response to all of the observations contained in the re-inspection report will preclude the need for re-inspection of the manufacturing facility by the FDA prior to approval. However, in accordance with FDA practice, the agency may re-inspect the facility at any time.

166. The April 18 8-K didn't tell the entire story. According to a transcript of the April 12 conference call with analysts, defendant Capetola acknowledged that the Totowa Facility had never "commercialized" a product before.

167. On April 19, 2006, the Company announced that it had entered into a new CEFF with Kingsbridge, which provided access to up to $50 million in equity over a three-year period. The new CEFF had a lower price threshold of $2.00 per share. Discovery Labs common stock closed that day at $4.28, which was below the $5.00 threshold that had been a component of the existing CEFF.

**Discovery Labs Discloses More Bad News About Surfacin®.**

168. On April 24, 2006, after the close of the market, the Company issued a press release which indicated as follows:

...analysis of ongoing stability data from Surfacin® process validation batches indicates that certain stability parameters have not been achieved and, therefore, additional process validation batches will likely have to be produced. These process validation
batches were previously manufactured as a requirement for Discovery's U.S. NDA regulatory approval and have been undergoing periodic stability testing. Discovery anticipates a potentially significant delay in the U.S. regulatory approval process for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants.

169. Stability testing assesses the ability of a drug to be stored without degrading and is regulated by the FDA as part of current Good Manufacturing Practices. The existing FDA regulations impose a requirement that drugs be subject to a written testing program designed to assess their stability; the results of stability testing “shall be used in determining appropriate storage conditions and expiration dates.” 21 C.F.R. § 211.166(a). As part of an NDA, in the Chemistry, Manufacturing and Controls section, an applicant, such as Discovery Labs, is required to include “stability data with proposed expiration dating.” 21 C.F.R. § 314.50(d)(1)(ii)(a). Stability testing was particularly significant for Surfaxin®, since the defendants had publicly indicated that they believed it could have a longer shelf life than existing surfactant products.

170. The market for Discovery Labs common stock reacted swiftly to this news. On April 25, 2006, the stock opened lower on the NASDAQ National Market System, and it closed that day approximately 53.09% lower on over twelve times the normal volume.

171. On May 4, 2006, the Company filed a registration statement on Form S-3 with the SEC, which described the status of the Surfaxin® NDA as follows:
In April 2006, we received from the FDA a second Approvable Letter related to our NDA for Surfaxin for the prevention of RDS in premature infants. The letter contained additional questions primarily related to Chemistry, Manufacturing and Control (CMC) areas and product labeling. We are currently analyzing the second Approvable Letter and preparing a comprehensive information package for the FDA addressing some of the issues in the second Approvable Letter. Once we have completed our analysis, we will request a meeting with the FDA and submit the comprehensive information package. Upon receipt of our request, procedurally the FDA must respond within 14 days and the meeting must occur within 75 days of the written request. At the meeting, we will seek to clarify the issues identified by the FDA in the second Approvable Letter. Thereafter, we will submit our formal response to the second Approvable Letter. At that time, the FDA will advise us of the time frame in which it will complete its review and advise us if it will accept our response to the second Approvable Letter as a complete response.

172. The May 4 S-3 furnished previously undisclosed details on the status of the Totowa Facility:

In December 2005, we purchased from Laureate Pharma, Inc., our contract manufacturer, its contract manufacturing operations and facility located in Totowa, NJ. This facility is our only validated clinical facility in which we produce clinical grade material of our drug substance for use in our ongoing clinical studies. The FDA concluded a three-week site re-inspection of our manufacturing facility on April 7, 2006. The focus of the FDA re-inspection centered on corrective actions implemented in response to the inspectional observations on Form 483 issued in January 2005, as well as ongoing manufacturing and quality control operations, systems and controls. Upon conclusion of the on-site inspection, the FDA issued a Form 483 containing inspectional observations related predominantly to the clarification of written procedures, documentation and preventive maintenance. We have submitted our response to the observations. One item noted on the site inspection Form 483 relates to certain drug product specification issues identified in the second Approvable Letter received in April 2006 and will be addressed in our response to the second Approvable Letter. Although the site inspection Form 483 does not cite a need for a re-inspection and we anticipate that our responses
to the Form 483 inspectional observations will be satisfactory to the FDA, the FDA may re-inspect our manufacturing facility at any time.

173. While the defendants had characterized the manufacturing process for Surfaxin® as straight-forward in the Company’s February 2005 release describing the FDA’s first inspection report on the Totowa Facility, they now characterized the process quite differently:

Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. Surfaxin is aseptically manufactured at our facility and presented as a sterile, liquid dispersion. The manufacturing process to produce Surfaxin is complex and requires ongoing monitoring of the stability and conformance to product specifications of each of the four active ingredients and must be conducted in a sterile environment. Each batch of drug produced at our manufacturing facility undergoes a stringent test regimen and a requisite number of lots per year are placed into a designed stability testing program consisting of specification testing conducted over multiple time intervals and storage conditions. A batch of drug product may fail to achieve the specified stability parameters. In April 2006, based on our stability testing program, we concluded that certain of the batches of Surfaxin that were identified in our new drug application (NDA) as “process validation batches” and manufactured in the period from June through August 2005 failed to achieve the designated stability parameters. We have initiated an investigation to determine the cause of the failure. Because these process validation batches are a part of our NDA, to complete our NDA, we will have to manufacture and designate new process validation batches and subject those new process validation batches to periodic stability testing. Accordingly, we anticipate a significant delay in the U.S. regulatory approval process for Surfaxin for the prevention of RDS in premature infants. We do not know at this time what exact impact this manufacturing issue will have on the Surfaxin European regulatory approval process, but such approval is likely to be delayed.
174. The same day, the Company filed a report on Form 8-K, in which it revealed that it had terminated the employment contract of defendant Schaber. Schaber was employed under a contract that had automatically renewed in January, so that the termination of his employment was not in the ordinary course. The May 4 release indicated that defendant Capetola was assuming direct responsibility for manufacturing, where Charles F. Katzer, Senior Vice President of Manufacturing Operations would report to him, and Quality Assurance, where Gerald J. Orehostky, Vice President of Quality Operations would report to him.

175. On May 10, 2006, Discovery Labs filed its quarterly report on Form 10-Q, which was signed by defendant Capetola. This 10-Q reported on the status of the Surfaxin® NDA as follows:

**Surfaxin Regulatory Approval**

In April 2006, the Company received a second Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. The Approvable Letter is an official notification from the FDA and contains conditions that must be satisfied by the Company prior to obtaining final U.S. marketing approval. Specifically, the FDA is requesting certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. Consistent with previous review, the FDA does not have any clinical or statistical comments.

The Company is currently analyzing the second Approvable Letter and preparing a comprehensive information package for the FDA addressing some of the issues in the second Approvable Letter. Once the analysis is completed and the manufacturing issues discussed above have been remediated, the Company will request a
meeting with the FDA and submit the comprehensive information package. Upon receipt of the Company’s request, procedurally, the FDA must respond within 14 days and the meeting must occur within 75 days of the written request. At the meeting, the Company will seek to clarify the issues identified by the FDA in the second Approvable Letter. Thereafter, and conditioned upon satisfactory Surfaxin process validation and stability, the Company will submit its formal response to the second Approvable Letter.

**Discovery Labs Withdraws from Europe.**

176. On June 6, 2006 (the last day of the Class Period), Peter Hagger, Director Of Global Regulatory Affairs at PRA International, forwarded a letter\(^1\) to Dr. Daniel Brasseur of the EMEA, which stated in relevant part as follows:

Dear Dr. Brasseur:

I would like to inform you, at this time, the applicant, PRA International, on behalf of the US sponsor, Discovery Laboratories, Inc. has taken the decision to withdraw the application for Marketing Authorization of SURFAXIN, 30 mg/mL, endotracheopulmonary instillation suspension, which was intended to be used for the prevention of respiratory distress syndrome (RDS) in premature neonates of less than 32 weeks of gestational age and for the treatment of RDS in premature neonates of less than 37 weeks of gestational age.

This withdrawal is based on identification of manufacturing and clinical issues which support the SURFAXIN application.

Discovery is addressing these issues and is committed to working with the EMEA to address the issues identified.

PRA and Discovery reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

Both PRA and Discovery agree for this letter to be published on the EMEA website.

Yours sincerely,

/s/ Peter Hagger

Peter Hagger
Director of Regulatory Affairs

177. That same day, Discovery Labs issued a press release announcing that it was withdrawing its Marketing Authorization Application which was pending before EMEA. The June 6 release, which was appended to a Form 8-K signed by defendant Capetola that was filed on June 7, 2006, stated in relevant part as follows:

**Warrington, PA — June 6, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO),** today announced that it has notified the European Medicines Evaluation Agency (EMEA) of its decision to voluntarily withdraw the Marketing Authorization Application (MAA) for Surfaxin® for the prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants. The decision to withdraw is based on recently announced manufacturing issues that Discovery has now determined cannot be resolved within the MAA review timetable. Withdrawal precludes resolution of certain outstanding clinical issues, which were the focus of a recent EMEA clinical expert meeting and relate to the Surfaxin Phase 3 clinical trials (including the design and lack of comparison to Curosurf®, the leading surfactant in Europe), that also may not have been resolvable within the current MAA review timetable. As a consequence, additional clinical trials may be required to support approval of Surfaxin for RDS in Europe through the centralized procedure.

Discovery’s New Drug Application to the United States Food & Drug Administration (FDA) is supported with data from Discovery’s Phase 3 SELECT and STAR trials. The FDA has issued Discovery a second Approvable Letter, which contains conditions that must be satisfied by Discovery prior to obtaining final U.S. marketing approval. Consistent with previous review, the FDA does not have any clinical or statistical comments.
Discovery previously announced that certain stability parameters from the Surfaxin process validation batches had not been achieved. As a result, additional process validation batches will have to be produced, which will take longer than the allotted MAA review timetable. The European centralized regulatory procedure does not provide a mechanism for placing an application on hold at this stage in the review process, or allow a company to add new information to the MAA. Discovery intends to have further discussions with the EMEA and develop a strategy for potential Surfaxin approval in Europe.

Discovery submitted the MAA in October 2004. The MAA submission was supported, in large part, by data from Discovery’s two positive Phase 3 RDS clinical trials. The SELECT study was a pivotal, landmark, adjudicated 1294 patient study that demonstrated Surfaxin’s superiority to Exosurf®, a non-protein containing synthetic surfactant. Survanta®, a cow-derived surfactant and the leading surfactant used in the United States, served as a reference arm in the SELECT trial. The multinational SELECT study demonstrated that Surfaxin was significantly more effective in the prevention of RDS and also improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. Discovery also conducted a 252 patient supportive study (STAR) that demonstrated Surfaxin’s non-inferiority to Curosurf, a pig-derived surfactant and the leading surfactant used in Europe.

This was the first time defendants ever hinted that there was any issue with the sufficiency of the clinical data submitted to support the Marketing Authorization Application. Even in disclosing the withdrawal of the Marketing Authorization Application, defendants failed to disclose that the Phase 3 clinical trials that the Company had conducted were not designed to meet EMEA’s clinical standards.

178. The price of Discovery Labs’ common stock dropped in response to the disclosure that the Marketing Authorization Application had been withdrawn, closing 19.28% lower on June 7, 2006.
SUBSEQUENT EVENTS

179. In an effort to down-play its difficulties, following the withdrawal of its Marketing Approval Application to the EMEA, Discovery Labs issued a series of press releases on other issues to give its future prospects a better appearance.

180. First, on June 15, 2006, the Company issued a press release indicating that the FDA had granted an Orphan Drug Designation to Surfaxin® for the prevention of Bronchopulmonary Dysplasia.

181. Second, on June 20, 2006, Discovery Labs issued a press release indicating that it had hired Jeffries & Company “to assist the Company in identifying and evaluating strategic alternatives,” including “potential business alliances, commercial and development partnerships, financings, business combinations and other similar opportunities.”

182. Third, on June 27, 2006, Discovery Labs issued a press release entitled “Discovery Labs Reports Progress on its Surfactant Manufacturing Remediation.” This June 27 release was appended as an exhibit to a Form 8-K that was signed by defendant Capetola and filed on June 27, 2007.

183. The June 27 release stated, in relevant part, as follows:

Warrington, PA — June 27, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today is reporting progress on its ongoing investigation into and remediation efforts for the April 2006 process validation stability failure related to its Surfaxin® (lucinactant) New Drug Application (NDA), including the attainment of some important investigative milestones. At this time, although the overall investigation is not complete, Discovery is optimistic that
appropriate remedial actions can be successfully implemented, providing a path to potential approval of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants in the United States.

Manufacturing Investigative Milestones and Next Steps

The comprehensive investigation was implemented immediately following the April 2006 stability failure of Surfaxin process validation that supported Discovery’s NDA. The investigation is being conducted in compliance with FDA current good manufacturing practices (cGMP) requirements and covers analysis of manufacturing processes; equipment and process validation; manufacturing components, drug substances and excipient manufacturers; review and assessment of out-of-specification and deviation reports; analytical methods and method validation; and change control documentation. The investigation will culminate in a comprehensive investigation report and a corrective and preventative action (CAPA) plan.

The investigation is ongoing and, at this time, it is not possible to anticipate or predict with certainty the timing or results of the investigation. Discovery reports the following progress to date:

- Discovery recently manufactured two investigation batches of Surfaxin that have passed all of the critical release specification assays, with the remaining release analytical procedures and stability monitoring ongoing. These investigation batches are intended to assess the impact of the investigative observations and will provide significant supportive data to the investigation report and the CAPA plan. These investigation batches are not designated as process validation batches.
- Discovery’s data and information gathering phase of the investigation is nearly complete. These data will support the investigation report and the CAPA plan. After a CAPA plan has been implemented, Discovery will meet with the FDA to clarify the issues identified in the second Approvable Letter and discuss Discovery’s plan to manufacture new process validation batches. It is Discovery’s goal to meet with the FDA and manufacture new process validation batches in the fourth quarter of 2006.
Discovery has been able, through the investigative process, to simultaneously address certain issues associated with the second Approvable Letter received from the FDA. Discovery believes that resolution of the manufacturing issues and implementation of a CAPA plan will also resolve a number of issues previously raised by the FDA in the second Approvable Letter.

In April 2006, Discovery received a second Approvable Letter from the FDA relating to its NDA for Surfaxin for RDS in premature infants. Issues contained in the second Approvable Letter primarily focused on the Chemistry, Manufacturing and Controls section of the NDA and product labeling. Most notably, the FDA did not require any additional clinical trials.

Over the years, Discovery has successfully manufactured numerous batches of Surfaxin, representing thousands of vials that achieved the desired stability profile. These batches included those used in Discovery’s highly successful Phase 3 clinical studies which demonstrate that Surfaxin was significantly more effective in the prevention of RDS and also improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. Discovery is conducting its investigation, in part, with reference to the manufacturing procedures that were used to produce those Surfaxin batches.

The investigation is led by Charles F. Katzer, Senior Vice President of Manufacturing Operations, and Gerald J. Orehostky, Vice President of Quality Operations. Mr. Katzer joined Discovery in January 2006 to oversee Discovery’s newly-purchased manufacturing facility in Totowa, NJ. Mr. Katzer has more than 30 years of broad functional experience in all aspects of manufacturing operations with major pharmaceutical and biopharmaceutical companies. He has extensive expertise in the sterile manufacture of liquids, injectables and aerosol dosage forms, product and process development, and process validation. Mr. Orehostky has approximately 20 years of diverse quality assurance and regulatory compliance experience with global pharmaceutical, biopharmaceutical and medical device companies.
184. On June 29, 2006, EMEA published a document on its website entitled *Questions and Answers on Withdrawal of Marketing Application for Surfaxin*

which stated in relevant part as follows:

> On 7 June 2006, Pharm Research Associates (UK) Limited has officially notified the Committee for Medicinal Products for Human Use (CHMP) that they wish to withdraw their marketing application for SURFAXIN, for the prevention and treatment of respiratory distress syndrome (RDS) in premature babies.

> SURFAXIN was designated as an ‘orphan medicine’ on 29 July 2004.

... .

What documentation was presented by the Company to support the application to the CHMP?
The effects of SURFAXIN were first tested in experimental models before being studied in humans. The company mainly presented the results of two studies on the prevention of RDS, involving over 1,500 premature neonates in total, where SURFAXIN was compared with other surfactant agents (one which has no protein component and two others which contain animal-derived protein). Effectiveness was measured by looking at frequency of RDS, survival with or without related pulmonary disorder (“bronchopulmonary dysplasia”), at different points in time.

How far into the evaluation was the application when it was withdrawn?
The application was at the stage of review of answers to remaining questions, adopted at around day 180, when the Company withdrew it. After the CHMP had assessed the responses from the Company to a list of questions, there were still unresolved outstanding issues.

The CHMP normally takes up to 210 days to evaluate a new application. Based on the review of the initial documentation, the CHMP prepares a list of questions (at day 120), which is sent to the Company. Once the Company has supplied responses to the

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questions, the CHMP reviews them and may, before giving an opinion, ask any remaining question(s) (at around day 180) to the Company. Following CHMP opinion, it usually takes around 2 months for the European Commission to grant an authorisation.

What was the recommendation of the CHMP at that time?
Based on the review of the data and the company's response to the CHMP list of questions at the time of the withdrawal, the CHMP had concerns and was of the provisional opinion that SURFAXIN could not be approved for the prevention and treatment of respiratory distress syndrome in premature babies.

What were the main concerns of the CHMP?
The main concern of the CHMP was related to the way the medicine is made, and in particular to the stability of the medicine. The CHMP was still questioning whether the design and the results of the studies were sufficient to establish that the product will be at least as effective and safe as other surfactant agents currently used to prevent RDS. Data to support the indication for the treatment of RDS were not sufficient. Therefore, at the time of the withdrawal, the Committee's provisional view was that the benefit had not been sufficiently demonstrated and did not outweigh the identified risks.

185. On July 28, 2006, Discovery Labs held a conference call with securities analysts. According to a recording of the call made available to the public, during the course of the call, in response to inquiries about the Marketing Authority Application in Europe from Katherine Xu of Pacific Growth Equities, defendant Capetola stated the following: The Phase 3 clinical trials for Surfaxin® had been designed in close consultation with the FDA. The scientific advice from the EMEA had been different from what Discovery Labs received from the FDA, and as a young biotech company, it could not pursue both approaches simultaneously. According to the recording, Capetola indicated that the
Company did not know what type of trial, such as a large non-inferiority trial, would be required by EMEA. When Ms. Xu asked a follow-up question on whether the STAR trial was sufficient for the EMEA, Capetola indicated that "it never was," and that "we designed that with the FDA."

**NO SAFE HARBOR APPLIES**

186. The statutory safe harbor for forward-looking statements does not apply to the disclosures at issue here, as the defendants' false and misleading statements related to the Company's current condition and business operations. Further, the safe harbor does not apply to the extent that the statements made either were not identified as "forward-looking statements" or did not refer to meaningful cautionary statements that could cause actual results to differ materially. Finally, the safe harbor does not apply to the extent that defendants lacked a reasonable basis for believing their forward-looking statements and did not believe them at the time they were made.

**SCIENTER ALLEGATIONS**

187. In connection with the false and misleading disclosures issued by Discovery Labs during the Class Period, defendants acted with *scienter*, as they knew that the Company's public disclosures were false and misleading or recklessly disregarded the truth.

188. Defendants were plainly aware of the problems with the Totowa Facility. Prior Form 483 and warning letters relating to the operation of the Totowa Facility were available from the FDA. They knew that there were
existing problems with the facility's compliance with current Good Manufacturing Practices and were cognizant that a failure to satisfy these standards would result in a delay in approval of the Surfaxin® NDA. Indeed, defendants purchased the facility outright and installed newly-hired manufacturing and quality control personnel in a belated effort to meet the FDA's standards. The decision to purchase the Totowa Facility was made shortly after the Company completed manufacture of the process validation batches under its NDA. Defendant Schaber was personally involved in the supervision of the Totowa Facility and reported directly to defendant Capetola. According to the recording of the July 28, 2006 conference call with analysts, the Company's Chief Financial Officer stated that operations at the Totowa Facility were central to the Company's business.

189. Defendants obviously knew that the Phase 3 clinical trials for Surfaxin® were not designed to meet EMEA's clinical standards, but they chose to withhold that information from investors.

190. Defendants had strong motives to conceal the truth about the Company's ability to manufacture Surfaxin® in compliance with current Good Manufacturing Practices, since Discovery Labs was in the process of raising equity financing during the Class Period, and the funds being raised were necessary for the Company to continue development of its products. During the Class Period, the Company engaged in the following financing transactions:
a. the April 2004 public offering of 2.2 million shares of common stock, which raised approximately $22.7 million in net proceeds;

b. the July 2004 transaction establishing the $75 million CEFF facility with Kingsbridge;

c. the November 2004 increase in the equipment leasing facility with GE of $6.5 million;

d. the December 2004 CEFF draw, which raised $7.2 million;

e. the February 2005 direct placement financing, which raised $27.4 million;

f. the September 2005 CEFF draw, which raised $17 million.

191. Absent successful conclusion of the Company's equity financing during the Class Period, Discovery Labs' ability to continue operations would have been impaired, and the value of the substantial stock options of defendants Capetola and Schaber would have been significantly reduced.

192. Defendant Capetola disposed of a substantial number of his shares at times relevant to this action. First, shortly before the Class Period began, despite the fact that Surfaxisin® had passed Phase 3 clinical trials and the Company was preparing to seek FDA approval, on February 27, 2004, defendant Capetola entered into a long-term prepaid forward contract, disposing of between 42.60% and 53.28% of his directly owned shares of the Company's common stock in return for over $4.7 million dollars in cash.
193. Second, shortly after the Class Period began, on March 18, 2004, defendant Capetola entered into another long-term prepaid forward contract, disposing of between 23.02% and 33.83% of his directly owned shares of the Company’s common stock in return for over $3.1 million in cash.

194. Just before the Company filed the NDA for Surfaxis®, defendant Schaber also decided to bet against the prospects for its approval. On April 7, 2004, defendant Schaber entered into a long-term prepaid forward contract, disposing of between 82.82% and 99.03% of his directly owned shares of common stock in return for over $2.3 million in cash.

COUNT I

195. The allegations of paragraphs 1 through 194 above are incorporated herein by reference. This Count arises under Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, and is asserted against all defendants.

196. In connection with offer and sale of securities, defendants intentionally or recklessly participated in the continuous course of conduct and employed devices, schemes or artifices to defraud members of the Class by publicly disseminating disclosures concerning the Company’s ability to manufacture its principal product in compliance with current Good Manufacturing Practices, and its prospects for the approval of Surfaxis® by the FDA.
197. In connection with offer and sale of securities, defendants intentionally or recklessly participated in the continuous course of conduct and employed devices, schemes or artifices to defraud members of the Class by publicly disseminating disclosures concerning the sufficiency of the data used to support the Company's Marketing Authorization Application with EMEA and the likelihood that Surfaxin® would be approved for sale in Europe.

198. In connection with the offer and sale of securities, defendants intentionally or recklessly omitted to state material facts necessary to make the statements made to Plaintiffs and the members of Class, in light of the circumstances under which they were made, not misleading.

199. In connection with the offer and sale of securities, defendants intentionally engaged in acts, practices or a course of business which operated as a fraud or deceit on Plaintiffs and the members of the Class.

200. Defendants acted with scienter as they knew that the public disclosures made in the name of the Company were false and misleading or recklessly disregarded the truth.

201. Plaintiffs and the other members of the Class were unaware of defendants' misconduct and of the misleading nature of the representations made in Discovery Labs' public disclosures.

202. Plaintiffs and the other members of the Class have been damaged as a result of defendants' misconduct, as the price of the Company's common stock was artificially inflated during the Class Period by reason of the false and
misleading disclosures of the defendants. The damages suffered by Plaintiffs and the Class were a direct and proximate result of defendants' wrongful acts, as demonstrated by the fact that the price of Discovery Labs' common stock collapsed on April 25, 2006, after the Company revealed its manufacturing problems, and dropped a substantial amount on June 6, 2006, when Discovery Labs announced its decision to withdraw its Marketing Approval Application for Surfacin® in Europe.

203. All defendants are liable to Plaintiffs and the Class pursuant to under Sections 10(b) of the Exchange Act, 15 U.S.C. §78j(b) and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

COUNT II

204. The allegations of paragraphs 1 through 203 above are incorporated herein by reference. This Count arises under Section 20(a) of the Exchange Act, 15 U.S.C. §78t(a) and is asserted against defendants Capetola and Schaber.

205. Defendants Capetola and Schaber were controlling persons of Discovery Labs under Section 20(a) of the Exchange Act, 15 U.S.C. §§78t(a), as they held senior positions with Discovery Labs and were directly involved in the development of Surfacin®. These defendants had the power and influence to control, directly or indirectly, the form, content and timing of Discovery Labs' disclosures concerning its manufacturing process for Surfacin®, the sufficiency of the data supporting the Marketing Authority Application in Europe, and the likelihood that Surfacin® would receive regulatory approval in the near future.
206. Defendants Capetola and Schaber were culpable participants in the Company's fraudulent conduct and did not act in good faith.

207. Defendants' Capetola and Schaber are therefore liable to Plaintiffs and the Class as controlling persons under Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

JURY DEMAND

208. Pursuant to Rule 38(a) of the Federal Rules of Civil Procedure, Plaintiffs hereby demand a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully request that the Court enter judgment as follows:

a. Declaring this action to be a proper class action maintainable pursuant to Rule 23 of the Federal Rules of Civil Procedure;

b. Appointing Plaintiffs as the representative of the Class and appointing Lead Counsel as counsel to the Class.

c. Awarding Plaintiffs and the Class compensatory damages;

d. Awarding Plaintiffs and the Class the costs and expenses incurred in this litigation, including reasonable attorneys' and expert witness fees; and
e. Granting Plaintiffs and the Class such other and further relief as the Court deems just and proper.

August 9, 2006

CHIMICLES & TIKELLIS LLP

By: /s/James R. Malone, Jr.
James R. Malone, Jr. (I.D. No. 41885)
Validation Code jrm263
Joseph G. Sauder (I.D. No. 82467)
361 West Lancaster Avenue
Haverford, PA 19041
(610) 642-8500 (telephone)
(610) 649-3633 (fax)

Lead Counsel

DURANT & DURANT LLP
Marc Durant (I.D. No. 15813)
325 Chestnut Street
Suit 1116
Philadelphia PA 19106
(215) 592-1818 (telephone)
(215) 592-9994 (fax)

Attorneys for Lead Plaintiff and the Proposed Class

LAW OFFICES BERNARD M. GROSS, P.C.
Deborah R. Gross (I.D. No. 44542)
Suite 450, John Wanamaker Building
Juniper and Market Streets
Philadelphia, PA 19107
(215) 561-3600

Attorneys for Plaintiff James F. Corey

and
MAGER & GOLDSTEIN LLP  
Carol A. Mager (I.D. No. 17548)  
One Liberty Place, 21st Floor  
1650 Market Street  
Philadelphia, PA 19103  
(215) 640-3280 (telephone)  
(215) 640-3281 (fax)

SCHATZ & NOBEL, P.C.  
Andrew M. Schatz  
Jeffrey S. Nobel  
Nancy A. Kulesa  
One Corporate Center  
20 Church Street, Suite 1700  
Hartford, CT 06103  
(860) 493-6292 (telephone)  
(860) 493-6290 (fax)

Attorneys for Plaintiff Claire Spooner
CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served this ninth day of August, 2006 via overnight courier, addressed as follows:

Robert L. Hickok, Esquire
Gay Barlow Parks Rainville, Esquire
Christopher J. Huber, Esquire
Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103

/s/ James R. Malone, Jr.
James R. Malone, Jr. (I.D. No. 41885)
Validation Code jrm263