This is a securities class action on behalf of all purchasers of the common stock of Alkermes, Inc. ("Alkermes" or the "Company") between April 22, 1999 and July 1, 2002 (the "Class Period"), against Alkermes and certain of its officers and directors for violations of the Securities Exchange Act of 1934 (the "1934 Act").

2. Alkermes is a biopharmaceutical company focused on the development of controlled-release drug delivery technologies and their application to existing or new drug therapies. Among the drug delivery technologies defendants seek to develop are sustained-release systems based on biodegradable polymeric microspheres, including those based on Medisorb polymers.

3. To demonstrate that the Medisorb-based technology had come of age, defendants signaled, at the very beginning of the Class Period, the achievement of an important milestone. Defendants announced that, despite a variety of challenges, they had succeeded in the development and scale-up of current Good Manufacturing Practices ("cGMP") production, using the Medisorb technology, of pivotal clinical lots for an important product candidate for the treatment of schizophrenia, Risperdal Consta.
4. During the Class Period, defendants assured investors of the promise of its Medisorb polymeric sustained-release delivery technology as an approach to improve the safety, tolerability and adverse effects of new or existing drugs. Defendants distinguished their sustained-release drug delivery system from oral formulations, pointing to several and certain serious concerns that were known to exist with the current tablet and oral-solution formulations, including anxiety, drowsiness, uncontrolled tremors and muscle stiffness, dizziness, constipation, nausea, upset stomach, runny nose, rash and rapid heartbeat.

5. During the Class Period, defendants further assured investors that the deal defendants made with Risperdal Consta joint venture partner JPI Pharmaceutical International ("Janssen") would be profitable to the Company, particularly since an agreement had been negotiated to secure, aside from the anticipated royalties and manufacturing payments under previous agreements, certain guaranteed financial payments and arrangements to eliminate significant financial risks.

6. During the Class Period, defendants artificially inflated the price of Alkermes shares by issuing a series of materially false and misleading statements about the Company's New Drug Application ("NDA") for Risperdal Consta.

7. The true facts, which were known by each of the defendants during the Class Period but were concealed from the investing public, were as follows:

   (a) In an attempt to decrease development expenses and speed the product to market, defendants concealed the deficient nature of the manufacturing process for Medisorb polylactide-glycolide ("PLGA") polymer used to manufacture Risperdal Consta, resulting in quality management issues and delays in the development program.

   (b) In order to conceal lot-to-lot variations resulting from the manufacturing process for Medisorb polymer, defendants minimized process development and validation requirements, including the establishment of specifications and analytical tests necessary to control those variations.
(c) Significant quality issues for the manufacture of Risperdal Consta existed at the Wilmington, Ohio facility, impacting the ability of the Company to meet clinical development timelines for Risperdal Consta.

(d) In order to avoid disclosure of the serious deficiencies of the Medisorb manufacturing process, particularly the lot-to-lot variation in molecular weight for Medisorb polymer, and in order to find a way to fix the desired molecular weight of the Risperdal Consta finished drug product, defendants patented a method to degrade the finished product to the desired molecular weight.

(e) Defendants' revenue projections for Risperdal Consta were grossly inflated based on defendants' concealment of the fact that Risperdal's adverse effects and safety or tolerability issues worsen when Risperdal is formulated using Medisorb technology and used as intended.

(f) Defendants concealed that due to the combined effect of the financial agreements reached with its joint venture partner, Janssen, Risperdal Consta would not be profitable unless it achieved the high end of sales projections, an unlikely outcome because of the worsening of Risperdal's adverse effects and safety or tolerability issues when the drug is formulated using Medisorb technology and used as intended.

(g) The serious safety concerns for Risperdal "oral" and Risperdal Consta "depot" products, such as cerebrovascular effects in elderly patients, extrapyramidal symptoms, QT interval prolongation and diabetes, which were detected in clinical trials that went unreported to worldwide regulatory authorities for long periods, in some cases for studies completed well before the beginning of the Class Period, were negatively impacting the regulatory review process.

(h) For one or more reasons related to the known but unmet manufacturing, safety or efficacy requirements for the drug, the NDA for Risperdal Consta would not be approved on July 1, 2002.

(i) The failure to disclose the defective nature of the Risperdal Consta chemical and manufacturing controls, clinical program, safety and other issues preventing the
Company from realizing product approval would prevent investors from learning the extent of
the misrepresentations made to them during the Class Period.

8. As a result of the defendants' false statements, Alkermes stock traded at inflated
prices during the Class Period, increasing to as high as $70.06 on February 16, 2000, whereby the
Company sold $200 million worth of its own securities.¹

9. On July 1, 2002, defendants announced the receipt of a non-approvable letter for
Risperdal Consta. As a result of this announcement, Alkermes' stock price dropped precipitously
over the next two days to a low of $4.04, or a loss of 93% from its Class Period high of $98 per
share, on total volume of 29 million shares.

JURISDICTION AND VENUE

10. Jurisdiction is conferred by §27 of the 1934 Act. The claims asserted herein arise
under §§10(b) and 20(a) of the 1934 Act and Rule 10b-5.

(a) Venue is proper in this District pursuant to §27 of the 1934 Act. Many of
the false and misleading statements were made in or issued from this District.

(b) The Company's principal executive offices are in Cambridge,
Massachusetts, where the day-to-day operations of the Company are directed and managed.

THE PARTIES

11. Plaintiff Paul Bennett purchased Alkermes common stock as described in the
attached certification and was damaged thereby.

12. Defendant Alkermes is a biopharmaceutical company focused on the discovery,
development and commercialization of new small molecule drugs for the treatment of
cardiovascular diseases. During the Class Period, defendants caused the Company to sell $200
million worth of its securities.

13. Defendant Richard F. Pops ("Pops") was Chairman and CEO of Alkermes.
During the Class Period, Pops sold 663,312 of his Alkermes shares, for net proceeds of $20.3
million.

¹All share and per-share amounts have been adjusted for Alkermes' 2-for-1 stock split in May
2000.
14. Defendant Robert A. Breyer ("Breyer") was President of Alkermes until December 2001 and is a director of the Company. During the Class Period, Breyer sold 522,375 of his Alkermes shares, for net proceeds of $14.7 million.

15. Defendant David A. Broecker ("Broecker") was Chief Operating Officer of Alkermes.

16. Defendant Michael J. Landine ("Landine") was Vice President of Corporate Development and a former CFO of Alkermes. During the Class Period, Landine sold 183,500 of his Alkermes shares, for net proceeds of $5.4 million.

17. Defendant James M. Frates ("Frates") was Vice President, Chief Financial Officer and Treasurer of Alkermes. Defendant Frates managed Finance, Intellectual Property, Investor Relations and Human Resources. In addition, he oversaw the pending acquisition of Reliant Pharmaceuticals, as well as Alkermes’ $200 million convertible bond issue. During the Class Period, Frates sold 86,000 of his Alkermes shares, for net proceeds of $2.8 million.

18. Defendant James L. Wright ("Wright") was Senior Vice President, Research and Development of Alkermes. During the Class Period, Wright sold 5,000 of his Alkermes shares, for a net proceeds of $164,000.

19. The individuals named as defendants in ¶¶13-18 are referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Alkermes' quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them but not to the public, each of these defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein at ¶¶34, 39, 41, 48, 50,
as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

**SCIENTER**

20. In addition to the above-described involvement, each Individual Defendant had knowledge of Alkermes' problems and was motivated to conceal such problems. Landine, as CFO, was responsible for financial reporting and communications with the market. Many of the internal reports showing Alkermes' forecasted and actual growth were prepared by the finance department under Landine's direction. Defendant Pops, as CEO and Chairman, was responsible for press releases issued by the Company. Wright, as Vice President of Research and Development, was responsible for development and manufacturing readiness. Each Individual Defendant sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market.

**FRAUDULENT SCHEME AND COURSE OF BUSINESS**

21. Each defendant is liable for (i) making false statements, or (ii) failing to disclose adverse facts known to him about Alkermes. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Alkermes common stock was a success, as it (i) deceived the investing public regarding Alkermes' prospects and business; (ii) artificially inflated the prices of Alkermes' common stock; (iii) allowed defendants to sell $200 million worth of Alkermes securities at artificially inflated prices; (iv) allowed Alkermes to enter into an agreement to complete its acquisition of Reliant Pharmaceuticals using Alkermes shares at artificially inflated prices; (v) allowed several defendants to sell their own shares at artificially inflated prices for insider trading proceeds of over $43 million; and (vi) caused plaintiff and other members of the Class to purchase Alkermes common stock at inflated prices.

**BACKGROUND AND OVERVIEW**

About the Company and the Drug

22. Defendant Alkermes is a biopharmaceutical company focused on the development of controlled release drug delivery technologies and their application to existing or new drug therapies. The Company's NDA for Risperdal Consta (depot product, depot formulation) for the
treatment of schizophrenia has been filed at the FDA. Risperdal (Risperidone) belongs to a class of compounds referred to as atypical antipsychotics, used in the treatment of schizophrenia. If approved by the FDA, Risperdal Consta would represent the first example of a sustained release or "depot" formulation for biweekly administration, to mitigate patient compliance issues.

23. The Risperdal Consta development effort is the result of a partnership between Medisorb Technologies International L.P. ("MTI") and Janssen. MTI entered into a development agreement with Janssen on or about December 23, 1993. Alkermes acquired the Risperdal Consta development program through the acquisition of MTI by its Alkermes Controlled Therapeutics Inc. II ("ACT II") subsidiary in 1996. The original development agreement was followed by two licensing agreements signed on or about February 21, 1996. The original development agreement was then amended on or about March 8, 1997 ("Second Amendment"). A definitive Manufacturing and Supply Agreement ("Mfg. Agreement") for a depot formulation of Risperidone was established on or about August 6, 1997. Other amendments and agreements occurred between the parties during the Class Period.

24. Within the Mfg. Agreement of 1997 are certain terms between the parties to address the responsibilities of the parties, including forecasting for the development and commercial production of Risperidone a "Manufacturing Readiness Plan" by which Alkermes would commit such resources and undertake such maintenance and training programs as needed to keep ACT II manufacturing facilities in a state of readiness for commercial manufacture of Risperidone. The 1997 Mfg. Agreement also covers quality and regulatory considerations, including the preparation and filing of a facilities Drug Master File ("DMF") with respect to the facilities where ACT II would manufacture the product and polymers.

25. The submission of a DMF is not required by law. A DMF is sometimes submitted to the FDA as a tool to protect confidential and detailed information about facilities, processes, or articles used in the manufacturing, processing, purchasing, and storing of drug products. DMFs allow a party other than the DMF holder to reference materials without disclosing to that party the contents of the file. The result is the maintenance of the confidentiality of the contents
to the DMF holder. The FDA will typically not review the substantive elements of the DMF until it is ready to review the IND, NDA or other application referencing the DMF.

26. Schizophrenia is a chronic, severe and disabling brain disease. Deterioration of brain matter can sometimes be detected or measured, and is particularly profound in children with early onset of the disease, affecting verbal memory, attention, reasoning, aggression and meaningful speech. According to the National Institute of Mental Health, approximately 1% of the world population suffers from schizophrenia in any given year. This suggests that as many as 2 million people in the United States are affected. Schizophrenia can be difficult to diagnose, but is usually manifested in a variety of so-called positive and negative symptoms. Positive symptoms are usually manifested as hallucinations or delusions that distort a person's sense of reality, often leading to paranoia. Negative symptoms are usually manifested as forms of isolation or withdrawal accompanied by poor personal hygiene or general lack of motivation. Combinations of positive and negative symptoms are possible.

27. The goal of a successful drug to treat schizophrenia is to inhibit and eliminate the mental, emotional, and behavioral disturbances associated with the disorder, with minimal side effects. Risperidone (Risperdal, 3-[2-[4-(6-Fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one) is a so-called "atypical" antipsychotic, a term reserved for the subclass of drugs having prominent antiserotonergic (5-HT2) as well as antidopaminergic (D2) and antihistaminic (H1) activities. Risperidone has the following structure:

![Risperidone Structure](image)

28. Risperdal Consta is a white powder made from Risperidone and 7525 DL JN1 poly-(d,l-lactide-co-glycolide) Medisorb polymer. The designation 7525 means that the polymer
is composed of lactide (A) and glycolide (B) units in a 75/25 ratio, in a random (unknown) sequence of "A" and "B" units. Polymers composed exclusively of A or B units have much slower rates of hydrolysis than polymers composed of mixtures of A and B units. Risperdal Consta is made by a combination of patented and proprietary processes that dissolve the Medisorb polymer, mix into it the Risperidone drug, and finally precipitate the polymer in the form of "microspheres." The microspheres are formed and processed in a sterile environment, whereby a known amount of powder is deposited in clean sterile vials. Critical to the process are methods to obtain the proper particle size of the microspheres and the uniform distribution of the drug in the polymer. Biweekly depot dosage forms currently available ex-U.S. include 25 mg, 37.5 mg and 50 mg. The 25 mg dosage form appears to be equivalent to a 2 mg oral dose.

29. According to ex-U.S. consumer information for the drug, Risperdal Consta is to be stored and used in the following manner: First, vials containing Risperdal Consta should be refrigerated at all times prior to use. To administer Risperdal Consta, the powder is diluted with an aqueous injection vehicle using a needle and syringe. The contents of the vial are shaken until a suspension is formed, appearing thick and milky in color. The entire contents of the vial is withdrawn, an appropriate needle is employed, air bubbles removed and, by application of proper technique, the entire contents of the syringe are injected intramuscularly into the buttock of the patient.

30. The release of Risperdal from the Risperdal Consta drug product may be described by an "in vivo release profile," the manner by which the drug entrapped in the Medisorb polymer matrix is released once the microspheres have been injected into the patient. For example, if the release profile demonstrates a "burst effect," releasing too much of the drug into the patient within a 24-hour period, the patient might experience an extremely high dose of the drug, followed by a lower linear release over time. Alternatively, the release profile could be sigmoidal in nature, characterized by an initial lag in the release of the drug from the Medisorb polymer matrix, followed by a steep intermediate release phase, and ending in a flat final release phase. The defendants have a patented technology that they may employ to control the in vivo release profile, as illustrated by the following in vitro cumulative drug release plot of Risperidone.
from Medisorb polymer, as a percent of total drug released from the microparticles (microspheres), as determined at specific timepoints:

![Graph showing cumulative release percentage over days for different drying conditions.

Safety of Risperdal Consta

31. The degree to which advantages with sustained or extended release drug formulations are realized is determined in part by safety considerations, including the ability to discontinue patient treatment when serious drug-related side effects are observed or when other critical medications capable of drug-drug interactions must be administered.

32. Alkermes reassured investors by explaining the advantages of and experience it has with its ProLease and Medisorb sustained-release drug delivery technologies on its Web site:

ProLease® and Medisorb® Injectable Sustained-Release Drug Delivery Systems

Alkermes® has developed two uniquely complementary platforms for drug delivery: ProLease and Medisorb injectable sustained-release technologies for both small and macromolecules. With release profiles lasting from days to months, each is designed to eliminate the need for frequent dosing. Each has the potential to:

- Improve patient compliance and convenience by reducing dosing frequency
- Improve safety and tolerability
- Reduce adverse effects associated with peak/trough levels of other (oral) dosage forms
- Commercialize products that would otherwise not be viable because of delivery or economic considerations
- Optimize product lifecycle management

The advantages are clear.

Each technology supports a broad array of applications and offers customizable release profiles lasting from days to months.

Alkermes has refined outstanding expertise in the kinetics of controlled release by generating predictable in vivo performances and clinically proven formulations.

With established commercial manufacturing facilities and all encompassing development infrastructure, Alkermes solidifies its position as a market leader in injectable sustained-release.

Alkermes' commitment to innovation brings product concepts to realization.

33. When the oral dosage form can cease to be administered or the dosage unit can be readily removed from the patient, as in the case of a transdermal patch, safety issues can be more readily addressed. When the formulation is designed as an implanted biweekly sustained-release dosage form, utilizing Medisorb polymer for sustained release of Risperdal, a drug known to defendants as having significant and serious side effects, potentially life-threatening safety issues could result from defendants' product design.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

34. On April 22, 1999, defendants issued a press release entitled "Alkermes and Janssen Pharmaceutica to Proceed into Phase III Clinical Trials of Sustained Release Formulation of Anti-Psychotic Drug Risperdal®." The press release stated in part:

Alkermes, Inc. announced today that Janssen Research Foundation, a division of Janssen Pharmaceutica, will proceed into Phase III clinical trials of an IM injectable sustained release formulation of the anti-psychotic drug RISPERDAL® (risperidone). The product candidate is based on Alkermes' Medisorb® drug delivery system and is designed to provide patients with prolonged therapeutic benefit from a single administration. The decision to proceed into Phase III clinical trials follows the successful completion by Janssen of Phase I and Phase II clinical trials of the product candidate and the completion by Alkermes of scale-up and Phase III manufacturing activities at the expected commercial scale.

"This is an important milestone in the development of this product candidate and of our Medisorb drug delivery technology," said Richard F. Pops, Chief Executive Officer of Alkermes. "We have moved rapidly in the
development and scale-up of this product candidate with our partners at Janssen Pharmaceutica. We look forward to the next phase of product development."

35. Defendants concealed the fact that the Medisorb facilities were comprised of two parts: the research and development operations in the "Blue Ash" facility located at 6954 Cornell Road in Cincinnati, Ohio, and the manufacturing facilities located approximately 35 miles north on Olinger Circle in Wilmington, Ohio.

36. While defendant Pops announced the production of manufacturing lots at commercial scale, the defendants concealed that the Wilmington facility was wholly unable to commence or maintain commercial scale operations for cGMP manufacture of Risperdal Consta or any other drug product. As of the April 22, 1999 press release, the only DMF in existence, established on March 15, 1990, was for the manufacture of Medisorb polymer at the Blue Ash facility in Cincinnati, Ohio. No such document had ever been filed for the Wilmington, Ohio facilities for the production of Medisorb injectable sustained-release drug delivery systems. Nor have defendants ever sustained a successful FDA pre-approval inspection in connection with the manufacture of any commercial drug products based on Medisorb sustained-release technology or in the Wilmington facilities.

37. Defendants also concealed quality issues with the 7525 DL JN1 poly-(d,l-lactide-co-glycolide) Medisorb polymer used in the production of Risperdal Consta manufacturing lots. Defendants knew that a uniform process of manufacture of polymer, achieving control over important quality parameters such as molecular weight, was critical. The decision not to routinely conduct tests for molecular weight on its Medisorb cGMP polymer lots concealed the fact that Medisorb polymer production methods resulted in molecular weights with an unacceptably wide variation from lot to lot for use in production of sustained-release drug delivery systems. Defendants knew at all times during the Class Period that: (i) polymer molecular weight affects drug release characteristics; (ii) the molecular weight of a polymer influences the biodegradation rate of the polymer; and (iii) polymer lot-to-lot variations can influence the in vitro and in vivo release profiles of the drug within a polymer matrix. In addition to the deficient state of the Wilmington manufacturing facilities, the April 22, 1999
press release failed to disclose the inadequate nature of the manufacturing process and controls for cGMP manufacture of Medisorb polymer lots that substantially contributed to the quality issues in the manufacture of Risperdal Consta research and clinical supplies during the Class Period.

38. In January 2000, defendant Breyer sold 200,000 Alkermes shares, defendant Frates sold 8,000 Alkermes shares, defendant Landine sold 99,000 Alkermes shares and defendant Pops sold 350,000 Alkermes shares at prices between $24.50 and $25.50 per share.

39. On February 16, 2000, at a time when the Company's shares were already trading at artificially inflated prices, the Company issued a press release entitled "Alkermes Announces Placement of $200 Million in Convertible Subordinated Notes." The press release stated in part:

Alkermes today announced the private placement of $200 million aggregate principal amount of its 3¾% Convertible Subordinated Notes due 2007. The offering, which was made through initial purchasers to qualified institutional buyers under Rule 144A under the Securities Act of 1933, is expected to close on February 18, 2000. Alkermes has also granted the initial purchasers of the notes an option to purchase up to an additional $50 million in principal amount of the notes. The notes are convertible into common stock of Alkermes at a conversion price of $135.50 per share, subject to adjustment in certain circumstances. Alkermes has agreed to file a registration statement for the resale of the notes and the common stock issuable upon conversion of the notes within 60 days after the closing of the offering.

40. News of the success of this badly needed financing reassured investors that the Company's products were viable and that the investment banking community stood behind the Company's science. Most importantly, as a result of this financial announcement, defendants convinced investors that the Company's success was assured, as shares spiked nearly 90% in value in the days that followed the announcement.

41. On May 19, 2000, defendants caused Application Ser. No. 09,575,075 to be filed with the U.S. Patent and Trademark Office for the grant of a patent entitled "Method for Preparing Microparticles Having a Selected Polymer Molecular Weight." Among the details describing the preferred embodiments of the invention was the following statement explaining the key use of the method:

The methods of the present invention control the hold time and temperature of a polymer solution in order to control the molecular weight of the polymer in the finished microparticle product. In this manner, the methods of the present
invention advantageously allow a selected polymer molecular weight to be achieved from a variety of starting material molecular weights. Alternatively, microparticle products of varying polymer molecular weights can be produced using the same molecular weight starting material. Thus, a range of products can be made from the same starting materials, thereby eliminating the need to reformulate the finished product to achieve the desired molecular weight of the polymer in the finished product.

42. By seeking the approval of the patent application on May 19, 2000, defendants sought to demonstrate expertise in the field and the capacity to create valuable intellectual property, while concealing a desperate need to identify product manufacturing methods to "fix" the quality issues relating to wide variations in the quality of Medisorb polymer required for the manufacture of Risperdal Consta.

43. Defendants knew that Medisorb PLGA polymers are actually composed of random (unknown) sequences of lactide (A) and glycolide (B) units, resulting in polymer strand regions with interspersed block (AB... AA... or BB...) sequences of unknown length. Defendants knew that degradation rates of PLGA polymers in solution have markedly different degradation rates, on the order of weeks or months, depending on the lactide/glycolide ratio, a fact critical to the polymer selection process and to the performance of a Medisorb sustained release PLGA based drug delivery system in vivo. Yet, despite defendants' knowledge of the critical nature of the lactide/glycolide ratio on the performance of Medisorb technology, defendants concealed the impact of the erosion process in the May 19, 2000 patent application, when applied to 75/25 Medisorb PLGA polymer having molecular weights ranging from 92 to 230 kiloDaltons (kD), on the lactide/glycolide ratio.

44. Defendants' use of a manufacturing scheme that included either or both of patented methods, first to "erode" or "degrade" the Medisorb polymer in an organic solution of the polymer containing Risperdal, and secondly to control the "burst effect," would further complicate defendants' efforts to achieve a cGMP compliant Risperdal Consta manufacturing process. The reason defendants sought new patented and proprietary processes that would actually complicate the Risperdal Consta manufacturing process was so that they could continue their concealment of quality issues relating to variation in the manufacturing process for the Medisorb polymer. Defendants sought these complications even though they realized that they
would create significant obstacles in achieving a controlled manufacturing process capable of validation, a key requirement for FDA inspection activities necessary to demonstrate readiness for manufacture of the product in the Wilmington facility.

45. In July 2000, defendant Breyer sold 75,000 Alkermes shares, defendant Frates sold 30,000 Alkermes shares, defendant Landine sold 40,000 Alkermes shares and defendant Pops sold 175,000 Alkermes shares at prices between $44.09 and $45.61 per share.

46. In September 2000, defendants' joint venture partner Janssen caused to be published a Review Article entitled "A Risk-Benefit Assessment of Risperidone for the Treatment of Behavioural and Psychological Symptoms in Dementia" ("Risk Assessment"). The article signaled the acceptability of the safety and efficacy profile of the drug for the treatment of dementia in the elderly. While the article was intended to disclose serious Risperdal side effects as part of a risk-benefit assessment, it actually concealed serious adverse cerebrovascular side effects ("CVAEs") in the elderly, contained in one or more Janssen studies cited as references to the article.

47. From January 2001 through July 2001, defendant Breyer sold 135,000 Alkermes shares, defendant Frates sold 20,000 Alkermes shares, defendant Landine sold 18,000 Alkermes shares, defendant Pops sold 55,000 Alkermes shares and defendant Wright sold 5,000 Alkermes shares at prices between $22.00 and $34.65 per share.

48. On or about August 1, 2001, defendants executed an Addendum to the Mfg. Agreement of 1997 ("Wilmington Facility Agreement"). The intent of this agreement was to recognize and remedy the fact that the Wilmington manufacturing facilities for the Risperdal drug product were inadequate and unready to undertake the cGMP manufacture of Risperdal Consta based on increased sales forecasts, once the product would be approved:

**ADDENDUM TO MANUFACTURING AND SUPPLY AGREEMENT**

This Addendum to Manufacturing and Supply Agreement (this "Addendum"), dated as of the 1st day of August, 2001 (the "Effective Date") is by and between JPI PHARMACEUTICA INTERNATIONAL, a division of Cilag AG International Zug, a company duly organized and existing under the laws of Switzerland, having its principal office in CH-6300 Zug, Kollerstrasse 38, Switzerland ("JPI") and JANSSEN PHARMACEUTICA Inc., 1125 Trenton-Harbourton Road, Titusville, NJ 08560, USA ("Janssen US" and,
together with JPI, "Janssen") on the one hand and Alkermes Controlled Therapeutics Inc. II, a company organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal office at 64 Sidney Street, Cambridge MA 02139-4136, USA ("ACTII") on the other hand.

WHEREAS, Janssen and ACTII have been collaborating for the development of a Risperidone depot formulation incorporating ACTII's proprietary technology concerning bioabsorbable polymer technologies and have entered into a Development Agreement and two License Agreements related thereto; and

WHEREAS, Janssen and ACTII entered into that certain Manufacturing and Supply Agreement, dated August 6, 1997 (the "Supply Agreement"), with respect to the commercial manufacture and supply of such Risperidone depot formulation to Janssen; and

WHEREAS, Janssen and ACTII desire to enter into this Addendum regarding the expansion of ACTII's manufacturing facilities, and the financial responsibilities of each of the parties in connection with such expansion, in order to support the increased sales forecasts for such Risperidone depot formulation; and

WHEREAS, Janssen and ACTII further desire to enter into this Addendum to formally provide for a collaborative effort to develop the manufacturing facility and commercial supply of Product.

49. Between August 1, 2001 and August 17, 2001, defendant Landine sold 4,000 Alkermes shares, defendant Frates sold 4,000 Alkermes shares, defendant Pops sold 12,500 Alkermes shares and defendant Breyer sold 12,000 Alkermes shares at prices between $26.46 and $27.92 per share.

50. On September 4, 2001, the Company issued a press release entitled "New Drug Application for First Injectable, Long-Acting Atypical Antipsychotic Submitted to FDA." The press release stated in part:

A new drug application for a long-acting injectable formulation of Risperdal® (risperidone)* has been filed with the Food and Drug Administration by Janssen Pharmaceutica Products, LP, and similar filings are now being submitted with health authorities worldwide. If approved, it would be the first atypical antipsychotic medication available in a formulation suitable for long-term use that requires administration just once every two weeks, instead of daily doses.

Using proprietary Medisorb® technology developed by Alkermes, Inc., the new formulation encapsulates risperidone in "microspheres" made of a biodegradable polymer, which is injected into the muscle. Laboratory and clinical research has shown that the microspheres gradually degrade at a set rate designed to provide consistent levels of the drug in the bloodstream. The polymer from which the microspheres are made breaks down into two naturally occurring compounds that are then eliminated by the body. Alkermes is scheduled to
manufacture this long-acting formulation of Risperdal pending regulatory approval.

Risperdal tablets, first introduced in the United States in 1994, have become the most widely prescribed atypical antipsychotic in the world, and the most commonly used antipsychotic of any type in the United States. It is indicated for the management of psychotic symptoms, such as those associated with schizophrenia—a brain disorder that affects about 1-2 percent of the world's population (including 2 million Americans). Older, conventional antipsychotics have been available in longer-acting, injectable formulations, which have been associated with significant side effects.

In its current tablet and oral-solution formulations, Risperdal has been shown in clinical trials to be effective and generally well tolerated. However, as with all antipsychotic medications, it was associated with side effects. In two controlled trials, adverse events that occurred in at least 5 percent of patients receiving Risperdal and were experienced at least twice as often as those taking placebo were anxiety, drowsiness, extrapyramidal symptoms (uncontrolled tremors and muscle stiffness), dizziness, constipation, nausea, dyspepsia (upset stomach), rhinitis (runny nose), rash and tachycardia (rapid heart beat). While dose-dependent, extrapyramidal symptoms typically occur at a rate that is comparable to that seen with placebo at doses less than or equal to 6 mg per day taken orally.

51. By signaling to investors in the September 4, 2001 press release that the Company stood ready to manufacture Risperdal Consta, defendants concealed the reasons for the August 1, 2001 Wilmington Facility Agreement and that the Wilmington facilities were in fact unable to begin commercial manufacture of the product at the expected levels.

52. Defendants' disclosure in the September 4, 2001 of the fact that all antipsychotic medications have been associated with side effects was false and misleading. In raising such broad-based concerns about antipsychotic medications, including longer-acting injectable formulations of conventional antipsychotics, defendants sought to conceal the special safety concerns that would accompany the use of Risperdal when formulated using Medisorb technology for sustained release. To note these special safety concerns would have differentiated the Medisorb-based depot product on the basis of safety, dramatically increasing concerns about product marketability, particularly in special populations, as well as for safe use in treating behavioural and psychological symptoms detailed in the false and misleading Risk Assessment article. These concerns would also have contradicted defendants' claims of the "clear advantages" resulting from the application of Medisorb technology posted on defendants' Web site:
ProLease® and Medisorb® Injectable Sustained-Release Drug Delivery Systems

Alkermes® has developed two uniquely complementary platforms for drug delivery: ProLease and Medisorb injectable sustained-release technologies for both small and macromolecules. With release profiles lasting from days to months, each is designed to eliminate the need for frequent dosing. Each has the potential to:

- Improve patient compliance and convenience by reducing dosing frequency
- Improve safety and tolerability
- Reduce adverse effects associated with peak/trough levels of other (oral) dosage forms
- Commercialize products that would otherwise not be viable because of delivery or economic considerations
- Optimize product lifecycle management

The advantages are clear.

53. On September 4, 2001, defendant Pops sold 7,812 Alkermes shares at $25.88 per share, and between October 24, 2001 and October 25, 2001, Pops sold 12,500 Alkermes shares at $25.01-$26.05 per share.

54. On September 4, 2001, defendant Landine sold 2,500 Alkermes shares at $25.88 per share, and between October 24, 2001 and October 25, 2001, Landine sold 4,000 Alkermes shares at $25.01-$26.05 per share.

55. Between September 4, 2001 and September 28, 2001, defendant Frates sold 4,000 Alkermes shares at $20.01-$25.88 per share and between October 3, 2001 and October 24, 2001, Frates sold 4,000 Alkermes shares at $20.53-$25.01 per share.

56. On September 4, 2001, defendant Breyer sold 7,500 Alkermes shares at $25.88 per share and between October 11, 2001 and October 25, 2001, Breyer sold 12,000 Alkermes shares at $22.67-$26.05 per share.

57. On October 30, 2001, the Company issued a press release entitled "Alkermes to Expand Production Facility to Meet Projected Demand for Long-Acting Formulation of Risperdal." The press release stated in part:

Alkermes, Inc. today announced the signing of an agreement with Janssen Pharmaceutica that provides for the expansion of Alkermes' manufacturing
capacity for production of the new, long-acting injectable formulation of Risperdal® (risperidone). A new drug application (NDA) for the new formulation of Risperdal, currently the most widely prescribed antipsychotic medication in the United States, was submitted to the U.S. Food and Drug Administration on August 31, 2001. Risperdal is expected to be the first "atypical" antipsychotic to be available in a formulation that only requires administration every two weeks.

"Our current manufacturing facility is fully equipped to support launch quantities and to meet the early demand projected for long-acting Risperdal," stated David Broecker, Chief Operating Officer of Alkermes. "This expansion will include the construction of a separate, large-scale GMP facility on the same site and is designed to enable Alkermes to significantly expand our production capacity. Our agreement with Janssen eliminates the financial risk associated with the acceleration of this expansion."

Pursuant to the agreement announced today, Alkermes has committed to expand its production capacity prior to FDA approval of the new Risperdal formulation in exchange for certain guaranteed financial payments. In addition, Alkermes will receive, under earlier agreements, royalties and manufacturing payments from Janssen upon successful commercialization of the new, long-acting Risperdal.

The long-acting formulation of Risperdal uses Alkermes' proprietary, injectable sustained-release drug-delivery technology, Medisorb®. The technology is based on the encapsulation of drugs into small polymeric microspheres that degrade slowly and release the medication at a controlled rate following subcutaneous or intramuscular injection. Alkermes is developing Medisorb product candidates in collaboration with pharmaceutical and biotechnology companies and on its own.

Nearly three months had elapsed between the signing of the Wilmington Facility Agreement and defendants' announcement in the October 30, 2001 press release. Despite the claims in the press release regarding the ability of the Wilmington manufacturing facilities to produce launch quantities and meet the early demand projected for the Risperdal Consta once the FDA approved the NDA, defendants again concealed the fact that the only DMF in existence for the MTI facilities, established on March 15, 1990, was for the manufacture of Medisorb polymer at the Blue Ash facility in Cincinnati, Ohio. No such document had ever been filed for the Wilmington, Ohio facilities for the production of Medisorb® injectable sustained-release drug delivery systems. Nor have defendants ever sustained a successful FDA pre-approval inspection in connection with the manufacture of commercial drug products in the Wilmington facilities. While a facilities DMF was not required under FDA regulations, the defendants were still required to produce and file one, by Janssen, under the 1997 Mfg. Agreement. Thus, despite
assertions to the contrary in the October 30, 2001 press release, defendants remained wholly unable to begin commercial manufacture of the product at the expected levels.

59. The October 30, 2001 press release regarding the elimination of the financial risk associated with the Wilmington Facility Agreement was false and misleading since it failed to point out that: (i) the costs of the project are to be borne exclusively by the defendants, and not by Janssen, unless Janssen terminates the development program; (ii) after commercialization, the costs of the project come out of defendants' royalty revenue, unless sales of the product fall below some minimum revenue amount; and (iii) defendants separately and egregiously accounted for the royalties and manufacturing payments from Janssen in connection with sales of the product as an additional source of revenue, as if these payments were wholly unconnected with the terms of the Wilmington Facility Agreement.

60. Between November 1, 2001 and February 26, 2002, defendant Landine sold 16,000 Alkermes shares, defendant Frates sold 16,000 Alkermes shares, defendant Breyer sold 54,000 Alkermes shares and defendant Pops sold 50,000 Alkermes shares at prices between $24.23 and $28.27 per share.


Alkermes, Inc., today announced that it added a poster to its website entitled "Maintenance of Efficacy Without Compromising Safety When Switching from Oral Risperidone to Risperdal Consta®, a Long-acting Injection Formulation of Risperidone." The poster was presented today, Tuesday, February 26, 2002 at 12:30pm ET at the Winter Workshop on Schizophrenia in Davos, Switzerland. This poster demonstrates the maintenance of efficacy without compromising safety when switching from Risperdal® (risperidone) tablets to Risperdal Consta. The poster is available on the Alkermes website at www.alkermes.com/news.

A new drug application (NDA) for Risperdal Consta was submitted to the U.S. Food and Drug Administration on August 31, 2001 by Johnson & Johnson Pharmaceutical Research & Development, which conducted the clinical-development program. If approved by the FDA, Risperdal Consta will be marketed in the United States by Janssen Pharmaceutica Products, LP and manufactured by Alkermes. Risperdal is currently the most widely prescribed antipsychotic medication in the United States and would be the first "atypical" antipsychotic to be available in a long-acting formulation. Risperdal Consta is a
long-acting injectable formulation of Risperdal that uses Alkermes' proprietary, injectable sustained-release drug delivery technology, Medisorb®. The technology is based on the encapsulation of drugs into small polymeric microspheres that degrade slowly and release the medication at a controlled rate following subcutaneous or intramuscular injection. Alkermes is developing Medisorb product candidates in collaboration with pharmaceutical and biotechnology companies and on its own.

62. The defendants knew that the press release of February 26, 2002 stating that the use of Risperdal Consta does not compromise patient safety was false and misleading, since the Risperdal Consta dosage form cannot not be removed once injected and there is no way to discontinue delivery of the drug in patients once they are afflicted with adverse side effects, whether or not they had already used oral Risperdal.

63. On March 21, 2002, the Company issued a press release entitled "Alkermes and Reliant Pharmaceuticals Announce Merger." The press release stated in part:

Alkermes, Inc. and Reliant Pharmaceuticals, LLC ("Reliant") today announced that the Board of Directors of Alkermes and the Board of Managers of Reliant have each unanimously approved a definitive merger agreement between the two companies. The merger unites Reliant's three marketed product brands, product development pipeline, extensive U.S. sales and marketing infrastructure and management team with Alkermes' advanced drug formulation and development capabilities, pipeline of proprietary and partnered products and manufacturing capabilities to create a rapidly growing integrated pharmaceutical company.

The transaction is structured as a tax-free exchange of equity, in which non-Alkermes equity holders of Reliant will receive a total of 31.07 million shares of Alkermes stock or approximately 31% of the outstanding shares of the new company post-closing. Based upon the March 20, 2002 closing market price for Alkermes of $30.05 per share, the purchase price for the portion of Reliant not already owned by Alkermes is $934 million.

THE DEFENDANTS' SCHEME BEGINS TO UNRAVEL

64. On July 1, 2002, the Company issued a press release entitled "Alkermes Announces Receipt by Johnson & Johnson Pharmaceutical Research & Development of Non-Approvable Letter for Risperdal Consta." The press release stated in part:

Alkermes, Inc. today announced that Johnson & Johnson Pharmaceutical Research & Development, LLC has received a non-approvable letter from the U.S. Food and Drug Administration (FDA) related to its New Drug Application (NDA) for Risperdal Consta(TM) (risperidone) long-acting injection.

"One of the strengths of our business model is the quality of the pharmaceutical companies with whom we collaborate," said Richard Pops, Chief Executive Officer of Alkermes. "Johnson & Johnson is one of the world's leading
health care companies. We have great confidence in relying on their ability and judgment in dealing with regulatory authorities around the world."

Risperdal Consta is a long-acting injectable formulation of Risperdal® that uses Alkermes' Medisorb® drug-delivery technology. If approved, Risperdal Consta will be manufactured by Alkermes and the product will be marketed by Janssen Pharmaceutica Products, L.P. in the United States, Janssen-Ortho in Canada and Janssen-Cilag elsewhere.


Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), today announced that it has received a non-approvable letter from the U.S. Food and Drug Administration (FDA) related to its New Drug Application (NDA) for RISPERDAL® CONSTATM (risperidone) long-acting injection. Issued at the 10-month goal FDA has set for responding to standard NDAs, the letter invited further dialogue with the agency to resolve questions regarding certain aspects of the pre-clinical data. No significant concerns were raised regarding the manufacturing process.

"We believe we will be able to satisfactorily resolve the FDA's questions about the pre-clinical data," said Harlan Weisman, M.D., executive vice president of research and development at J&JPRD. "We look forward to doing so in an expeditious manner and moving ahead with the approval process."

RISPERDAL® CONSTATM is a long-acting injectable formulation of RISPERDAL® that uses Alkermes' proprietary, injectable, extended-release, drug-delivery technology, Medisorb®. The technology is based on the encapsulation of drugs into small polymeric microspheres that degrade slowly and release the medication at a controlled rate following subcutaneous or intramuscular injection. If it is approved, RISPERDAL® CONSTATM will be manufactured by Alkermes and marketed in the United States by Janssen Pharmaceutica Products, L.P.

"We believe RISPERDAL® CONSTATM will represent an important new treatment option for persons with schizophrenia by offering all of the benefits of an atypical antipsychotic in a long-acting form," Dr. Weisman continued. "It has been estimated that as few as 25 percent of persons with schizophrenia take their medication on a consistent basis—a problem that can lead to relapse and re-hospitalization. Because of its two-week duration of effect, thus eliminating the need for daily pills, RISPERDAL® CONSTATM may help increase adherence to treatment."

66. Together, the disclosures of July 1, 2002, point to unresolved medical issues, such as those relating to safety and efficacy of the Risperdal Consta drug product. While the Johnson & Johnson disclosure indicated that there were no significant issues presented regarding the
manufacturing process, defendants failed to note in their press release that they were still unable to begin commercial manufacture of the product for the U.S. markets at the expected levels. While at a very late stage of the NDA process, for a product that allegedly presented no significant issues regarding the manufacturing process itself, defendants were still at the earliest stage of refocusing their Wilmington research and development operations into an elaborate, highly automated commercial manufacturing facility, with plans to begin validation activities at the end of the third quarter 2002. Thus, despite assurance of no significant manufacturing process issues in the July 1, 2002 Johnson & Johnson press release, the Wilmington facilities were in fact still wholly unable to begin commercial manufacture of the product for the U.S. markets at the expected levels.

67. As a result of defendants' announcement of the non-approvable letter for Risperdal Consta on July 1, 2002, Alkermes' stock price dropped precipitously over the two-day period following the announcement, from a high of $16.01 to a low of $4.04, or a drop of 74.8%, on total volume of 29 million shares.

POST CLASS PERIOD REVELATIONS

Failed Merger

68. On August 14, 2002, Reliant Pharmaceuticals terminated its merger agreement with Alkermes. While defendants had expected to consummate the transaction based on the overly inflated value of the Company's stock, they could not control the timing of the FDA's issuance of a rejection letter for Risperdal Consta.

Stroke and Death in the Elderly

69. On October 17, 2002, the Health Products and Food Branch of Health Canada issued the following notice to healthcare professionals, entitled "Updated Safety Information for Risperdal (Risperidone) in Elderly Dementia Patients, Announced in Canada":

Further to discussions with Health Canada, Janssen-Ortho Inc. advised healthcare professionals of new safety information for the use of RISPERDAL (risperidone), an antipsychotic medication in elderly, dementia patients. The manufacturer has notified doctors and pharmacists of reports of strokes and stroke-like events in clinical studies in elderly patients with dementia taking RISPERDAL.
Data were analyzed from four clinical studies in elderly, dementia patients. In two of these studies, a higher proportion of patients taking RISPERDAL experienced strokes or related events than did those who received placebo (sugar pill). Further information from ongoing analyses of clinical studies will be posted as it becomes available.

Worldwide exposure to RISPERDAL in elderly, dementia patients is approximately 2.5 million patient years. From this patient population, there have been 37 reports of strokes or stroke-like events (1 in Canada), including 16 deaths (1 in Canada). Generally, there is an increased risk of strokes and stroke-like events in the elderly population.

Patients or their caregivers should immediately report to their doctors any signs and symptoms of potential strokes such as sudden weakness or numbness in the face, arms or legs, and speech or vision problems. Patients or their caregivers should inform their doctors of their past and present medical history, including history of stroke or stroke-like events, and should also consult their doctor prior to making any changes in their medication.

Information about this safety update has been sent to doctors and pharmacists to ensure that they are aware of this new safety information when prescribing and dispensing RISPERDAL. The company is working with Health Canada to update the Canadian prescribing information for RISPERDAL. In the interim, all healthcare professionals are advised to review the healthcare professional letter.

70. The CVAE results of certain clinical studies cited by Health Canada were not discussed in the Risk Assessment article of September 2000, nor were they addressed in the July 1, 2002 disclosures. Despite these omissions, the CVAEs of Risperdal were considered to be so serious that, once discovered by regulatory authorities, warnings were required by Canadian and U.S. authorities to protect the health and welfare of elderly patients taking Risperdal. Defendants knew but concealed the fact that this warning would have a serious negative impact on the market for and approvability of Risperdal Consta, since defendants knew it would be impossible to discontinue or withdraw, once administered, a deep intramuscular injection of the Risperdal Consta biweekly dosage form in the event that signs and symptoms of potential CVAEs were reported by elderly patients.

Tardive Dyskinesia

71. The Risk Assessment article of September 2000 also noted a single case of de novo tardive dyskinesia in a clinical study involving 413 patients. The August 9, 2002 U.K. product approval press release failed to note the potential for tardive dyskinesia side effects while using Risperdal Consta. A warning for tardive dyskinesia appearing on the U.S. package insert
for oral and liquid dosage forms of Risperdal since 1999 provides a recommendation that withdrawal of the Risperdal drug therapy be considered should the symptoms of tardive dyskinesia appear. In such circumstances, the alternative use of Zyprexa or Clozaril has been reported. Tardive dyskinesia, a known Risperidone-induced side effect, is a syndrome marked by involuntary movement of the lips or jaw and certain other dystonic gestures. Defendants knew but concealed the fact that if tardive dyskinesia was observed by a patient who was prescribed Risperdal Consta, it would be impossible for a healthcare provider to comply with the recommendation indicated on an approved U.S. package insert for current Risperdal dosage forms, to withdraw, once administered, a deep intramuscular injection of the Risperdal Consta biweekly dosage from patients afflicted with the drug-induced syndrome.

**Extrapyramidal Symptoms**

72. The defendants produced all clinical trial supplies used in clinical studies reported in the article entitled "The First Antipsychotic of the 2nd Generation in a Depot Form: Risperidone Microspheres in Intramuscular Injections," published in the *Journal Psychiatrie* ("Psychiatrie Paper") during the second half of 2002. The paper is summarized as follows:

**Summary**

Risperidone is the first antipsychotic of the 2nd generation that is distributed in depot injections. Intramuscular application leads to therapeutic plasma levels within 3-4 weeks – this is also the period for which risperidone has to be simultaneously administered perorally in the beginning of treatment. The depot injections reach steady-state plasma concentrations without major fluctuation or high peaks of maximum levels following the application.

Risperidone in the depot form was tested in five 3-4 month trials, 3 of which were open and 2 double-blind, and in a single long-term, 50-week study, in which the total of 1892 patients treated for schizophrenic and schizoaffective disorders were involved. Risperidone depot injections were more effective than placebo and equally effective as the oral form of the same drug in influencing not only the positive, but also the negative and affective symptoms and in normalising the scores of the quality-of-life scale. 17.6% of patients were rehospitalised during the one-year treatment and the length of inpatient treatment was significantly shorter.

*The most frequent side-effects included extrapyramidal reactions observed in 20-30 % of patients depending on the application dose,* hyperprolactinemia, mild weight gain, and in 10-15 % of patients also headache, somnolence and dyspepsia.
Risperidone in the depot form is a preferential choice for maintenance therapy of patients with schizophrenic and schizoaffective disorders who refuse oral administration of drugs or repeatedly discontinue therapy.

73. Extrapyramidal symptoms or EPS are characterized by stiffness, rigidity, uncontrollable tremors, involuntary movements, restlessness and other symptoms and are a serious problem associated with antipsychotic medications. **EPS are believed to have a major impact on patient compliance, especially for the majority of schizophrenia patients who are on long-term treatment.** Defendants knew but concealed the fact that, paradoxically, the use of the Medisorb sustained-release delivery system with Risperdal **almost doubles** the occurrence of EPS, **while actually making it impossible for afflicted patients to discontinue treatment**, since it would be impossible to discontinue or withdraw, once administered, a deep intramuscular injection of the Risperdal Consta biweekly dosage form in the event EPS arise.

74. The FDA-approved U.S. package insert indicates that EPS is an adverse event experienced with the use of Risperdal oral formulations. As many as 3.8% of patients treated with Risperdal discontinued use because of extrapyramidal symptoms in controlled clinical trials. Notably, the statement of the author of the Psychiatrie Paper actually belies the safety-based limitations on the marketability of Risperdal Consta by adopting a position that forces the use of the depot form of the drug on those patients who refuse Risperdal, **when extrapyramidal symptoms would cause them to refuse Risperdal therapy:**

Risperidone in the depot form is a preferential choice for maintenance therapy of patients with schizophrenic and schizoaffective disorders who refuse oral administration of drugs or repeatedly discontinue therapy.

75. The results reported in the Psychiatrie Paper, of clinical studies necessary for product registration activities, point to the concealment by defendants during the Class Period of the facts relating to known clinical experience with Risperdal side effects that would have an exceptional impact on the marketability of the drug, including (i) **whether or not Risperdal Consta can be safely given to patients absent prior patient experience with the drug**; (ii) **whether or not a period of safe use with oral formulations of Risperdal must be established prior to administration of Risperdal Consta**; and (iii) **whether or not these issues stood in the way of the successful achievement of defendants' product revenue and profitability goals.**
76. The lowest ex-US dosage form of Risperdal Consta currently available, 25 mg, is equivalent to a 2 mg daily oral dosage. The FDA-approved U.S. package insert summarizes data demonstrating the dose-relatedness for the triggering of extrapyramidal symptoms associated with Risperdal treatment. Thus, a higher prescribed dose of Risperdal or an inadvertent acute overdose of Risperdal can trigger EPS. Defendants also knew, based on the FDA-approved U.S. package insert that the enzyme responsible for metabolism of risperidone to 9-hydroxyrisperidone is actually a family of polymorphic enzymes capable of wide variation in metabolic rates by race and that no definitive pharmacokinetic studies looking at differences in dosage requirements by race and gender have been performed for Risperdal. Defendants knew but concealed the fact that EPS would be an even more serious side effect for a depot form of Risperdal, by collaborating with its joint venture partner in the overseas marketing of the drug with the following warning in the event of "overdose," provided for in the U.K.-registered package insert for Risperdal Consta:

Symptoms:

In general, reported signs and symptoms have been those resulting from an exaggeration of the drug's known pharmacological effects. These include drowsiness and sedation, tachycardia and hypotension, and extrapyramidal symptoms. In overdose, rare cases of QT-prolongation have been reported. In case of acute overdose, the possibility of multiple drug involvement should be considered.

Treatment:

Establish and maintain a clear airway, and ensure adequate oxygenation and ventilation. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias.

There is no specific antidote to Risperdal. Therefore appropriate supportive measures should be instituted. Hypotension and circulatory collapse should be treated with appropriate measures such as intravenous fluids and/or sympathomimetic agents. In case of severe extrapyramidal symptoms, anticholinergic medication should be administered. Close medical supervision and monitoring should continue until the patient recovers.

Arrhythmia and Sudden Death

77. Torsades de Pointes is a syndrome of polymorphic ventricular tachycardia occurring in the setting of marked prolongation of the electrocardiographic QT interval. It occurs
in individuals genetically predisposed to the disorder and is a frequent cause of sudden death in these individuals. Defendants knew that adverse pro-arrhythmic effects linked to QT interval prolongation were of concern to the FDA and that as many as 40 marketed drugs, including Risperdal and a similar number of drugs under development have been found to prolong the QT interval. Drug induced Torsades de Pointes is a relatively rare event but can be as high as 2% to 3% with some drugs.

78. Defendants noted instances of tachycardia (rapid heart beat) in their press release of August 9, 2002, but failed to address how Risperdal Consta patients experiencing QT interval prolongation would be treated. Defendants were aware of the February 7, 2002 draft guidance entitled "Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals." This guidance concludes that, while recognizing that clinical data related to the measurement of QT interval prolongation is important, efforts must also focus on nonclinical and preclinical aspects predictive of the condition. Despite this knowledge, defendants concealed the fact that if QT interval prolongation would be experienced by a patient who was prescribed Risperdal Consta, it would be impossible for a healthcare provider to discontinue treatment, since it is impossible to withdraw, once administered, a deep intramuscular injection of the Risperdal Consta biweekly dosage from patients afflicted with QT interval prolongation.

**Drug-Drug Interactions**

79. Drug-drug interactions are also an important safety concern. These interactions can occur when two or more drugs interact with each other. It is generally known that the need to administer selective serotonin uptake inhibitors such as Zoloft or Prozac can slow the metabolism of Risperdal, resulting in Parkinson-like symptoms. Defendants concealed the fact that, in contrast to oral dosage forms, it would be impossible for a healthcare provider to immediately withdraw a deep intramuscular injection of the Risperdal Consta dosage form, even if the patient is faced with therapeutic needs and requirements incompatible with Risperdal therapy.
Diabetes: Risperdal Not An Exception

On Monday, August 25, 2003, Erica Goode, a human behaviour staff writer for The New York Times ("NYT"), authored the following newspaper article in the NYT regarding the risk of diabetes resulting from the use of Risperdal, entitled "3 Schizophrenia Drugs May Raise Diabetes Risk, Study Says." The article stated in part:

Three drugs commonly prescribed for schizophrenia and other psychotic illnesses increased patients' risk of developing diabetes when compared with older antipsychotic medications, researchers said yesterday, presenting the results from a long-awaited study of patients treated at veterans hospitals and clinics across the country.

The drugs – Zyprexa, made by Eli Lilly, Risperdal, made by Jannsen Pharmaceutica, and Seroquel, made by AstraZeneca – were associated with higher rates of diabetes than older generation drugs for schizophrenia like Haldol, the study found. But the increased risk was statistically significant only for Zyprexa and Risperdal, the researchers said, possibly because of the smaller number of subjects in the study who took Seroquel.

Younger patients, under age 54, who took Zyprexa or Risperdal showed the highest risk of developing diabetes, the study, led by Francesca Cunningham of the Department of Veterans Affairs at the University of Illinois at Chicago, found.

The results add to a growing number of reports linking Type 2 diabetes to some drugs in the class of antipsychotics known as atypicals.

"These findings are absolutely consistent with everything we've looked at and seen," said Robert Rosenheck, a professor of psychiatry and public health at Yale and an author of an earlier study that found an increased risk of diabetes with Zyprexa, Risperdal, Seroquel and Clozaril, made by Novartis.

Experts said the new findings underscored the need for patients who take the drugs and doctors who prescribe them to be alert for the symptoms of diabetes, including increased thirst, frequent urination, increased appetite or rapid weight gain.

Atypical antipsychotics, studies indicate, are less likely than older drugs to produce side effects like tardive dyskinesia, a devastating movement disorder. The newer drugs also appear more effective in preventing relapse in patients with schizophrenia and may be more effective in treating certain aspects of the illness.

More than 15 million prescriptions were written last year for Zyprexa and Risperdal, the two leading atypical antipsychotics, according to industry figures.

Researchers in the last two years have found higher rates of diabetes and hyperglycemia, medical conditions that are usually reversible, among patients taking the newer drugs. But many of the studies have been based on case reports in medical journals or filed voluntarily by doctors with the Food and Drug Administration, making it difficult to determine the size of the problem or whether it is associated with particular drugs or with the class of drugs as a whole.
The new study, scientists said, is important because of its careful methodology and substantial size: the researchers based their analyses on medical records from 19,878 veterans treated with an older or newer drug between October 1998 and October 2001.

Of 5,981 veterans who took Zyprexa, 200, or 3.34 percent, developed diabetes, compared with 170, or 2.43 percent, of 7,009 veterans taking Haldol or another older medication. Of 5,901 patients taking Risperdal, 193, or 3.27 percent, developed diabetes; 21, or 2.39 percent, of 877 veterans taking Seroquel developed the illness. All three drugs raised a patient's chances of developing the illness by about 50 percent, but the meaning of the increased risk among patients taking Seroquel was unclear because of the smaller number of subjects who took the drug, the researchers said.

"We need a larger number of observations to be certain what its risk is and whether it differs from other drugs," said Bruce Lambert, an associate professor of pharmacy administration at the University of Illinois at Chicago and an author of the study.

The study was financed in part by Bristol Myers Squibb, the maker of Abilify, an atypical that had not entered the market when the study began and has not been systematically studied for a link to diabetes.

* * *

Laura Bradbard, a spokeswoman for the F.D.A., which has been tracking the diabetes issue, said the agency was reviewing the new findings, which were presented yesterday in Philadelphia at a meeting of the International Society for Pharmacoepidemiology ....

The agency is considering whether to add or strengthen warnings in the labeling of certain drugs or on the class of drugs as a whole.

How atypical antipsychotics might produce or uncover diabetes is unknown. Weight gain, a side effect of some drugs, may play a significant role, researchers believe. But P. Murali Doraiswamy, chief of the division of biological psychiatry at Duke University, said that in some cases the illness has come on rapidly, before patients have time to gain weight.

81. Despite earlier public assurances that Risperdal was found to be an exception to the increased risk of diabetes posed by certain atypical antipsychotics, defendants sought to conceal the serious negative impact on the market for and approvability of Risperdal Consta that would inevitably follow a link to diabetes.

82. The true facts, which were known by each of the defendants during the Class Period but were concealed from the investing public, were as follows:

(a) In an attempt to decrease development expenses and speed the product to market, defendants concealed the deficient nature of the manufacturing process for Medisorb
PLGA polymer used to manufacture Risperdal Consta, resulting in quality management issues and delays in the development program.

(b) In order to conceal lot-to-lot variations resulting from the manufacturing process for Medisorb polymer manufacture, defendants minimized process development and validation requirements, including the establishment of specifications and analytical tests necessary to control those variations.

(c) Significant quality issues for the manufacture of Risperdal Consta existed at the Wilmington, Ohio facilities, impacting the ability of the Company to meet clinical development timelines for Risperdal Consta.

(d) In order to avoid disclosure of the serious deficiencies of the Medisorb manufacturing process, particularly the lot-to-lot variation in molecular weight for Medisorb polymer, and in order to find a way to fix the desired molecular weight of the Risperdal Consta finished drug product, defendants patented a method to degrade the finished product to the desired molecular weight.

(e) Defendants' revenue projections for Risperdal Consta were grossly inflated based on defendants' concealment of the fact that Risperdal's adverse effects and safety or tolerability issues are worsened when Risperdal is formulated using Medisorb technology and used as intended.

(f) Defendants concealed the combined effect of the financial agreements reached with its joint venture partner, Janssen, that Risperdal Consta would not be profitable unless it achieved the high end of sales projections, an unlikely outcome because of the worsening of Risperdal's adverse effects and safety or tolerability issues when the drug was formulated using Medisorb technology and used as intended.

(g) The serious safety concerns for Risperdal "oral" and Risperdal Consta "depot" products, such as CVAEs in elderly patients, extrapyramidal symptoms, QT interval prolongation and diabetes, which were detected in clinical trials that went unreported to worldwide regulatory authorities for long periods, in some cases for studies completed well
before the beginning of the Class Period, were negatively impacting the regulatory review process.

(h) For one or more reasons related to the known but unmet manufacturing, safety or efficacy requirements for the drug, the NDA for Risperdal Consta would not be approved on July 1, 2002.

(i) The failure to disclose the defective nature of the Risperdal Consta chemical and manufacturing controls, clinical program, safety and other issues preventing the Company from realizing product approval would prevent investors from learning the extent of the misrepresentations made to them during the Class Period.

**FIRST CLAIM FOR RELIEF**

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

83. Plaintiff incorporates ¶¶1-82 by reference.

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

85. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Alkermes common stock during the Class Period.

86. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Alkermes common stock. Plaintiff and the Class would not have purchased Alkermes common stock at the price they paid, or at all, if they
had been aware that the market price had been artificially and falsely inflated by defendants' misleading statements.

87. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Alkermes common stock during the Class Period.

SECOND CLAIM FOR RELIEF
For Violation of §20(a) of the 1934 Act Against All Defendants

88. Plaintiff incorporates ¶¶1-87 by reference.

89. The Individual Defendants acted as controlling persons of Alkermes within the meaning of §20(a) of the 1934 Act. By reason of their positions as officers and/or directors of Alkermes, and their ownership of Alkermes stock, the Individual Defendants had the power and authority to cause Alkermes to engage in the wrongful conduct complained of herein. Alkermes controlled each of the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Alkermes are liable pursuant to §20(a) of the 1934 Act.

CLASS ACTION ALLEGATIONS

90. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Alkermes common stock (the "Class") on the open market during the Class Period. Excluded from the Class are defendants.

91. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, Alkermes had more than 54 million shares of stock outstanding, owned by hundreds if not thousands of persons.

92. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) Whether the 1934 Act was violated by defendants;
(b) Whether defendants omitted and/or misrepresented material facts;
(c) Whether defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
(d) Whether defendants knew or deliberately disregarded that their statements were false and misleading;
(e) Whether the price of Alkermes common stock was artificially inflated; and
(f) The extent of damage sustained by Class members and the appropriate measure of damages.

93. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

94. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

95. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:
A. Declaring this action to be a proper class action pursuant to FRCP 23;
B. Awarding plaintiff and the members of the Class damages, interest and costs; and
C. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: October 28, 2003

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Attorneys for Plaintiff
CERTIFICATION OF NAMED PLAINTIFF
Pursuant to Federal Securities Laws

PAUL BENNETT ("Plaintiff"), declares as to the claims asserted, or to be asserted, under the federal securities laws, that:

1. Plaintiff has reviewed the Alkermes, Inc. complaint and authorized its filing.

2. Plaintiff did not purchase any common stock/securities that are the subject of this action at the direction of Plaintiff’s counsel or in order to participate in any private action under the federal securities laws.

3. Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary. I understand that this is not a claim form, and that my ability to share in any recovery as a member of the class is not dependent upon execution of this Plaintiff Certification.

4. The following includes all of Plaintiff’s transactions during the Class Period specified in the complaint for the common stock/securities that are the subject of this action:

<table>
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<tr>
<th>SECURITY</th>
<th>TRANSACTION</th>
<th>QUANTITY</th>
<th>TRADE DATE</th>
<th>PRICE PER SECURITY</th>
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<td>Purchase</td>
<td>180</td>
<td>8-10-01</td>
<td>$26.35</td>
</tr>
</tbody>
</table>

Please list additional transactions on a separate sheet if necessary.

5. Plaintiff has not sought to serve or served as a representative party for a class in an action filed under the federal securities laws within the past three years, unless otherwise stated in the space below:

6. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond Plaintiff’s pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this ___ day of October, 2003.

[Signature]