UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

[redacted] on Behalf of Himself and All Others Similarly Situated, Plaintiffs, vs. ACURA PHARMACEUTICALS, INC., ANDREW D. REDDICK, PETER A. CLEMENS, RON J. SPIVEY AND ROBERT JONES, Defendants.	No. CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

INTRODUCTION AND OVERVIEW

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of the publicly traded securities of Acura Pharmaceuticals, Inc. ("Acura" or the "Company") between February 21, 2006 and April 22, 2010 (the "Class Period"), who were damaged thereby (the "Class").

2. Acura and its wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc. engage in the research, development, and manufacture of pharmaceutical product candidates that utilize Acura's proprietary Aversion Technology, Impede Technology, and other technologies that purportedly provide abuse deterrent features to orally administered pharmaceutical drug products containing abusable active ingredients, such as tranquillizers, stimulants, sedatives, decongestants, and various other opioid analgesics.

3. The Company's lead product candidate during the Class Period, "Acurox," was an orally administered immediate release tablet containing oxycodone as its active analgesic ingredient. Acura's opioid analgesic product candidates were purportedly designed to relieve pain while discouraging common methods of opioid product misuse and abuse, including intravenous injection of dissolved tablets or capsules; nasal snorting of crushed tablets or capsules; and intentional swallowing of excess quantities of tablets or capsules.

4. Acurox, Acura's immediate release formulation of oxycodone, contained niacin (a B vitamin) purportedly as an aversive agent (or deterrent) to prevent "swallowing excess quantities of tablets." Acurox also employed other non-pharmacological mechanisms to deter nasal ingestion and to limit the potential for conversion into a form suitable for intravenous administration.

5. Oxycodone is a schedule II narcotic marketed either alone in ***controlled release*** form (OxyContin), in single-entity ***immediate release*** formulations (Roxicodone and generics),

or in combination with nonnarcotic analgesics such as aspirin (Percodan) or acetaminophen (Percocet). There are over 80 schedule II oxycodone products approved in the U.S. including generics. However, there were only a limited number of single entity oxycodone products that did not also contain non-narcotic pain relievers (acetaminophen or aspirin). Of the 7,185,000 prescriptions of these single-entity oxycodone products sold in 2000, approximately 5.8 million were for OxyContin (or 81% of the single entity product market). As such, the market for single-entity ***immediate release*** formulations (Roxicodone and generics) ***that did not contain aspirin*** (Percodan) or acetaminophen (Percocet), ***both of which would counteract the niacin deterrent effect***, was quite limited.

6. Moreover, because doctors tended to only prescribe immediate release formulations (Roxicodone and generics) to treat pain in post-surgery patients, the abuse potential for ***immediate release*** oxycodone products was dramatically less than the potential for abuse of ***controlled release*** versions of oxycodone. Defendants knew the niacin effects were easily overcome by abusers who knew to simply eat a heavy meal or take aspirin with the Acurox. Defendants also knew but concealed that non-abusers taking niacin-laden Acurox were approximately twice as likely to suffer adverse niacin side effects, such as flushing, nausea, headaches and vomiting, as non-abusers taking unadulterated oxycodone. As such, defendants knew physicians were less likely to prescribe oxycodone – even if FDA approval were possible – which they knew was not the case. This, in turn, made it imperative for defendants to convince the investment community that the FDA would permit defendants to at least describe Acurox as providing a deterrent effect in its product label, even if they could not list it as an approved indication, so the market would believe Acurox was commercially viable.

7. Indeed, knowing the FDA had specifically advised defendants that an aspirin trial should be run, defendants refused to do so because they knew the data would show that aspirin completely mitigated the niacin effects, which would make Acurox more easy to abuse and hence the Company could not receive the deterrent labeling defendants sought. Meanwhile, defendants repeatedly conveyed to the investment community throughout the Class Period that the FDA was not requiring additional clinical trials, that based on what defendants knew then the FDA would permit them to describe Acurox's deterrent effects in its product label, and promised investors that Acurox was a feasible FDA 502(b)(2) bioequivalent drug candidate when they knew all along the niacin additive rendered the drug non-approvable because only non-abusers would experience the adverse niacin effects while abusers could easily avoid them.

8. Acura's filings with the Securities and Exchange Commission ("SEC") at the start of the Class Period indicated that the Company "convened a face-to-face meeting" with the FDA in early 2006 – meetings where these issues should have been self-evident. Yet, following this "face-to-face" meeting and other interactions with the FDA throughout the Class Period, the Company repeatedly claimed that its clinical drug trials were effectively designed and administered, its drug formulation effectively deterred drug abuse in drug abusers, the adverse niacin effects would not interfere with the intended therapeutic pain relief the oxycodone was intended to provide, that the FDA had stated in writing Acurox was a proper candidate for FDA Section 505(b)(2) approval based on bioequivalence to another tested and proved drug (instead of requiring a more costly and time-consuming full-scale FDA trial) and that the FDA had indicated in writing the Company would be able to describe Acurox's its deterrence efficacy in its product label, purportedly demonstrating the drug's commercialization potential.

9. By misrepresenting Acurox's potential for obtaining FDA approval and the Company's other drug products during the Class Period, Acura obtained a lucrative third-party license agreement that allowed it to obtain tens of millions of dollars worth of milestone payments; obtained a listing on the Nasdaq Stock Exchange; and obtained a coveted listing on the Russell 3000 Index. The Company's senior executives named as defendants herein also obtained hundreds of thousands of dollars in cash bonuses for signing the licensing agreement and causing Acura to obtain milestone payments on that licensing agreement – payments only made possible by their deception. Moreover, the value of the Acura common stock held by the Company's venture capital financiers – substantial majority controlling shareholders – was artificially inflated both by the defendants' false statements and the stock listings, increasing the reported value of these investors' holdings during the Class Period, and thus strengthening their own balance sheets.

10. However, when the FDA's pre-ordained decision to reject the Company's Acurox new drug application ("NDA") by a vote of 19-to-1 was finally disclosed to the market between April 20, 2010 and April 22, 2010, including, its well-founded reasons fordoing so, the Company's stock price plummeted and nearly 50% of the Company's market capitalization simply vanished. These decreases in Acura's stock price were the result of the artificial inflation caused by defendants' misleading statements coming out of the stock price.

11. Specifically, the FDA's April 20, 2010 "Executive Summary" expressly disclosed that:

(a) Concerning the study's failure to demonstrate that the niacin flushing reaction would not, as defendants had claimed, inordinately subject non-abusers who were already in pain to additional needless discomfort that could contravene the positive benefits of the oxycodone pain reduction therapy, the FDA's Executive Summary concluded that "[w]hile

the oxycodone component in Acurox is efficacious, ***the Agency has concerns about the use of niacin. The niacin component, added to deter drug abuse, appears to negatively affect the adverse event profile of this drug. The incidence of flushing in the Acurox clinical development program for subjects taking oxycodone + 60 mg of niacin ranged from 12% to 77% compared to 1.5% with placebo***." Essentially, the FDA found that patients using Acurox in Acura's clinical trials were far more prone to being nauseous and vomiting to the point where they were having to take other drugs to stop the symptoms. Specifically, "antiemetics" are drugs that are used to reduce nausea and vomiting. The FDA found four patients on the placebo took these drugs while a whopping 135 patients on Acurox had to take these drugs. Acurox as a medication in whole was supposed to relieve pain, yet patients taking the drug were throwing up and feeling nausea, when patients taking regular immediate release oxycodone demonstrated a far better side effect profile.

(b) The FDA also found the niacin contradictions clearly outweighed its benefits. The FDA specifically found the "[a]pplicant failed to justify the inclusion of niacin under the Combination Drug Regulation," for at least the following reasons: (i) "In the fasted state, ***the niacin doses tested were not particularly aversive***"; (ii) "NSAIDs and aspirin ***are known to mitigate niacin-induced flushing***. Whether aspirin or an NSAID would have mitigated the effects of Acurox could have been elucidated in a clinical trial, ***as recommended by the Agency. The Applicant did not include pretreatment with aspirin in abuse liability studies***. In the absence of data to the contrary, ***the logical assumption*** is that pretreatment with cyclo-oxygenase inhibitor would likely blunt any vasodilatory reaction."

(c) Concerning the debilitating effects on non-abusers, the FDA's Executive Summary also expressly disclosed that "[a]lthough flushing has been reported with use of oxycodone, it is an adverse event that is more frequently associated with niacin. ***In the pivotal controlled clinical trial, the Applicant did not include an oxycodone-only arm, so it is difficult to sort out how much of the reports of flushing in the active arms was due to oxycodone or***

niacin. However, the available evidence supports the conclusion that the high rates of flushing are primarily a consequence of exposure to niacin, not the oxycodone."

(d) Despite defendants' repeated claims of abuse deterrence efficacy throughout the Class Period, including Acura's express statements that based on the clinical data the Company provided the FDA, the FDA had stated in writing the drug was approvable under the FDA's 505(b)(2) NDA process and that the FDA had expressly approved in writing the Company's requested product labeling describing the drugs' purported deterrent effect, the FDA's Executive Summary concluded ***"[t]he Agency also has concerns about the ability of niacin to act as a deterrent to abuse.*** To evaluate the dose that would create a deterrent effect of niacin, the applicant conducted niacin dose-finding studies in healthy volunteers. ***The results suggest that niacin offers little in the way of deterrence to oral abuse as even at high doses of niacin***, the mean scores for niacin tolerability did not approach the most unfavorable score, 'Unpleasant and difficult to tolerate.' These studies also included an evaluation of the effect of food and found that the aversive effects observed in the fasted state were easily mitigated by food." ***Essentially, though the oxycodone was effective at relieving pain, the niacin additive was not effective at deterring abuse.***

(e) Critically, the FDA's Executive Summary also concluded as to Acurox's deterrence efficacy that "[b]ecause it is known that aspirin and non-steroidal agents are able to greatly decrease the flushing reaction associated with niacin . . . ***the Division requested that the applicant conduct a study that assessed the effects of co-administration of aspirin, but this was not done."***

(f) Finally, the FDA said ***"it is known that the flushing associated with the use of niacin can lessen over time and, in Study 103, subjects appear to have developed tolerance to niacin within 10 days."*** Essentially, ***any*** deterred effect would be short-lived. [Emphasis added.]

12. Following the April 22, 2010 announcement that the FDA would not approve Acurox, investors learned for the first time that the FDA had expressly advised defendants in

July 2009 that the level of adverse reactions to the niacin additive rendered Acurox inherently non-approvable. The FDA also emphasized that defendants' own pre-clinical data and clinical data developed during the Class Period (and before) affirmatively negated their oft-repeated Class Period claims that Acura was a viable candidate for FDA 502(b)(2) approval and that based on what they knew at the time they made their public statements, defendants had a good faith basis to state the FDA would allow Acura to claim deterrent properties in its product label. As such, defendants knew throughout the Class Period Acurox would never be a commercially viable product.

JURISDICTION AND VENUE

13. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("1934 Act") and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. Acura's headquarters is located in Des Plaines, Illinois, and false statements were made in this District and acts giving rise to the violations complained of occurred in this District.

THE PARTIES

14. Plaintiff, [redacted] ("Plaintiff") purchased Acura's publicly-traded securities during the Class Period as set forth in the attached certification and was damaged thereby.

15. Defendant Acura is a specialty pharmaceutical researcher and manufacturer. Acura was founded in 1935 and is based in Palatine, Illinois. Acura's stock is traded under the symbol ACUR on the Nasdaq Stock Exchange, which is an efficient market.

16. Defendant Andrew D. Reddick ("Reddick") was, at all relevant times, President, Chief Executive Officer ("CEO") and a Director of the Company. Previously, from April 2000 to September 2002, Reddick served as chief operating officer and sr. vice president commercial operations for Adolor Corporation.

17. Defendant Peter A. Clemens ("Clemens") was, at all relevant times, Senior Vice President, Chief Financial Officer ("CFO"), Secretary and a Director of the Company.

18. Defendant Ron J. Spivey ("Spivey") was, at all relevant times, Senior Vice President and Chief Scientific Officer of the Company.

19. Defendant Robert B. Jones ("Jones") was, since April 2008, Chief Operating Officer ("COO") and a Senior Vice President of the Company. Previously, from May 2003 to March 2008, Jones served first as the vice president, finance and then as vice president, strategy and business analysis of Adolor Corporation.

SCIENTER

20. During the Class Period, the defendants had both the motive and opportunity to conduct fraud, as further detailed *infra*. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of Acura publicly traded securities during the Class Period.

BACKGROUND TO THE CLASS PERIOD:
ACURA'S AUSPICIOUS BEGINNINGS AS "HALSEY DRUG COMPANY"

21. Acura was originally founded as Halsey Drug Company, Inc. ("Halsey") in New York in 1935. Halsey, based in Brooklyn, New York, manufactured generic drugs and its stock began trading publicly in the mid-1980s.

Halsey's Felony Conviction for FDA Violations

22. Following a run-up in the Company's stock price from approximately $20 per share throughout the late 80s to over $100 per share by early 1993, on July 12, 1993, Frederick Shainfeld ("Shainfeld"), a former Senior Vice-President of Halsey was indicted on charges of

conspiracy to impede the U.S. Federal Drug Administration's ("FDA") regulatory function, interstate distribution of adulterated and unapproved new drugs, making false statements to the FDA and obstruction of an FDA inspection. Shainfeld eventually admitted he and others at Halsey created and gave to the FDA inspectors records that fraudulently misrepresented certain research and development batch sizes that the FDA required to ensure that a company can, in fact, manufacture production quantities of a drug according to the approved formula.

23. In reality, Halsey had been making smaller batches, then falsely claiming they were the required size. When the FDA investigated, Shainfeld and others, including former President and Chief Executive Officer Jay Marcus ("Marcus"), ordered employees to create false inventory records to hide the fact that Halsey had insufficient raw materials to make the batches in the size they represented. In addition, evidence at the trial of Hedviga Herman, Halsey's former Vice-President of Manufacturing, showed that Halsey added unapproved ingredients to certain drugs and falsified records to cover up those additions. The drugs included quinidine gluconate, which is used to treat heart arrhythmias; metronidazole, used to treat serious infections; and propylthiouracil, used to treat hyperthyroidism. Shainfeld and Marcus sanctioned the falsifications.

24. Herman was convicted June 2, 1993 and sentenced to 18 months' imprisonment on September 23, 1994. Marcus pleaded guilty and was sentenced to 41 months imprisonment on October 24, 1994. Finally, Shainfeld, who was in charge of Halsey's Technical and Regulatory Affairs section, pleaded guilty on May 4, 1994 and was sentenced on January 9, 1994 to 18 months imprisonment and fined $5,000 for obstructing an FDA investigation of Halsey. ***On July 16, 1993, Halsey itself pleaded guilty to five felony counts of adulterating a heart medication, quinidine gluconate in 324 milligram tablets, and was fined $2.5 million.***

Halsey's Securities Fraud Violations

25. Following its own investigation, on January 28, 1997, the SEC instituted proceedings against Halsey ***and permanently enjoined the Company from violating the federal securities laws .***

26. According to the SEC's findings, Halsey's ability to develop and manufacture new generic drug products depended, in large part, on the Company's ability to gain approval from the FDA. To obtain FDA approval, the ingredients and manufacturing processes that Halsey used were prescribed by formulas that were submitted to and approved by the FDA. To ensure that drugs were produced in accordance with the approved formulas, the Current Good Manufacturing Practices, 21 C.F.R. – 110, *et seq.* ("CGMP"), required Halsey to contemporaneously write and maintain accurate records documenting the raw materials used and manufacturing processes followed for each batch of generic drug products produced.

27. The SEC found that Halsey filed an annual report on Form 10-K with the Commission on April 1, 1991 for the year ended December 31, 1990 ("1990 10-K") and on April 14, 1992 for the year ended December 31, 1991 ("1991 10-K") and that Halsey's 1990 10-K and 1991 10-K stated that Halsey had to follow CGMP at all times during which an FDA-approved drug was manufactured by the Company. The 1990 and 1991 10-Ks further stated that in order to comply with the CGMP, Halsey had to "expend time, money and effort in the areas of production and quality control to ensure full technical compliance."

28. In so doing, the SEC found that Halsey's 1990 and 1991 10-Ks failed to disclose that Halsey was not manufacturing generic drugs in accordance with CGMP because it was using unapproved formulas and procedures and that Halsey employees, at management's direction, were taking steps to conceal product adulteration from the FDA. These annual reports also failed

to disclose that since Halsey was not manufacturing generic drugs in accordance with CGMP, FDA approval for any or all of Halsey's new products could be adversely affected.

29. Citing Halsey's June 21, 1993 plea of guilty to a five-count criminal information charging that in September 1992, Halsey shipped adulterated drugs in interstate commerce, specifically admitting that it failed to comply with CGMP by causing the preparation and maintenance of false production records and caused the manufacture of a certain drug using a non-FDA approved formula (*United States v. Halsey Drug Co., Inc.*, Cr. No. HAR-93-0285 (D. Md. June 21, 1993)), the SEC found that Halsey committed violations of Sections 10(b) and 13(a) of the 1934 Act, and Rules 10b-5, 12b-20, and 13a-1 thereunder, by filing annual reports on Form 10-K for the years ended December 31, 1990 and 1991 that 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.

Halsey's Management Overhaul and Name Change to Avoid Investor Scrutiny

30. Following a complete management turnover and a massive restructuring, in 2001, the Company attempted to become a commercial bulk importer of "opioids." Opioids are narcotics such as raw opium, opium poppy and concentrate of poppy straw. Despite the Company's already diminished reputation and standing in the reputation-sensitive U.S. drug industry, Acura's senior executives sought to obtain DEA licensure to import opioids and then to manufacture and sell opioid-based pharmaceuticals. Halsey filed its application for registration to import narcotic raw materials with the U.S. Drug Enforcement Administration ("DEA") on January 31, 2001 and notice of the Company's application was published in the Federal Register on September 6, 2001. ***Immediately, multiple objections to Halsey's license were filed with the DEA.*** Following an evidentiary hearing before a DEA Administrative Law Judge in August

2003 and Halsey's November and December 2003 announcements that it was again restructuring and undergoing refinancing activities, the evidentiary record was closed on May 25, 2004. Suspecting the DEA licensing for an opioid import license would not be forthcoming, Halsey abandoned its efforts to obtain licensure to import narcotic raw materials altogether. Meanwhile, as had occurred in the early 90s prior to its 1993 felony conviction, Halsey's stock price more than doubled between 2001 and 2003 on the market's positive expectations of a turn around but again plummeted below $10 per share in connection with the resolution of the evidentiary hearing process.

31. Meanwhile, in August 2003, Reddick, the former Chief Operating Officer and Sr. Vice President Commercial Operations for Adolor Corporation, was appointed President and CEO of Halsey. On April 7, 2008, Jones, who had previously served as the Vice President, Finance and then as Vice President, Strategy and Business Analysis of Adolor with Reddick, would also join as Senior VP and COO of the Company. While these Individual Defendants had only joined Acura after its felony conviction and SEC enforcement action, Reddick and Jones had recently jumped ship from Adolor, another company accused of defrauding its investors at the time they left, and thus were well aware of the strictures of the federal securities laws.

32. As later alleged by civil litigants in *Adolor* securities fraud class action (*In re Adolor Corporation Securities Litigation*, Civ. Action No. 04-CV-1728, Amended Complaint for Violations of the Federal Securities Laws filed (E.D. Pa. March 1, 2005), ***like Halsey/Acura, Adolor too was a developmental stage biopharmaceutical corporation attempting to develop and commercialize products to relieve pain, while reducing the side effects of then-currently marketed narcotics.*** Like Acurox, Entereg, also known as alvimopan, was Adolor's lead pharmaceutical product candidate throughout the April 2, 2003 to December 22, 2004 class

period in the *Adolor* action. Entereg had not been approved by the FDA for the treatment of any condition.

33. In April 2002, Adolor entered into an agreement with GlaxoSmithKline ("Glaxo") to collaborate on the worldwide development and commercialization of Entereg as a treatment for postoperative ileus ("POI"). POI is a serious complication that occurs in connection with abdominal and other surgical procedures. The clinical consequences of POI include abdominal bloating, distention, or pain, postoperative nausea, vomiting and gastrointestinal dysfunction. POI is considered a major contributor of postoperative morbidity. According to plaintiffs in the *Adolor* action, Adolor's executives too made a series of materially false and misleading representations concerning the clinical program supporting an NDA for and commercialization of Entereg as a treatment for POI.

34. Specifically, they alleged three clinical trials of Entereg were to be performed by Adolor, commonly referred to as the "302," "313" and "308" trials, which were conducted in that order. The "313" study did not enroll simple hysterectomy patients, while the "302" and "308" studies did. According to the *Adolor* plaintiffs, Adolor's executives (1) concealed that simple hysterectomy patients, who would make up a large portion of the potential market for Entereg, did not respond to the drug in the "302" study, (2) falsely represented that they had not broken out study results by patient type in their earliest "302" study, despite the fact that each study site only enrolled one type of patient, (3) falsely represented that the "302" study was "blinded" and "randomized," as defendants had not randomized patients among study centers and knew which patients in which study centers had been treated with Entereg and which patients had responded to treatment ("study center bias"), and (4) rigged the results of the "313" study by improperly taking advantage of the "study center bias" learned of during the "302" study and manipulating

methods of statistical analysis applied to the study. Furthermore, according to the *Adolor* plaintiffs, Adolor's executives knew, but concealed from investors, that the lack of response in simple hysterectomy patients in the "302" study and the rigging of the "313" study indicated a high risk of failure in the "308" study and a study of Entereg for POI being performed in Europe by Glaxo. The concealed data demonstrated that the drug lacked any real benefit for simple hysterectomy, bowel resection and other abdominal surgery patients, the very classes of patients that defendants claimed the drug could benefit.

35. According to the *Adolor* plaintiffs, defendants' misrepresentations throughout ***that*** class period deceived the medical and investment communities about the scope and utility of Entereg as a potential new treatment for POI. As a consequence, they alleged the market price of Adolor common stock was artificially inflated during their class period. According to the *Adolor* plaintiffs, as a result of the Adolor executives' misrepresentations about the "302," "313" and "308" studies, ***Adolor was able to file a NDA with the FDA, requiring Glaxo to pay Adolor $10 million under the terms of their Collaboration Agreement.***

36. However, on January 13, 2004, Adolor reported that Entereg failed to achieve statistically significant results against the primary endpoint of the "308" study, the third in the series of Phase III clinical trials for the company's planned NDA submission. The news shocked investors, as the drug had purportedly been successful on the primary endpoint in the prior two studies. Based on the disclosure of the "308" study results, the price of Adolor's stock plunged 37%. Yet according to the *Adolor* plaintiffs, Adolor's executives continued to conceal that the lack of efficacy in simple hysterectomy patients was the root cause of mixed results in the "302" and "308" studies, and that Entereg had demonstrated success on the primary endpoint in the "313" study only because that study had been rigged based on the defendants' knowledge of

"study center bias" from their "302" study. Finally, on December 23, 2004, only three months after Adolor announced that the FDA had accepted the defendants' Entereg NDA for filing and review, the company disclosed the failure of an Entereg European phase III clinical trial performed by Glaxo for the POI indication.[1] The Glaxo trial, like the "313" study, did not enroll simple hysterectomy patients, but only bowel resection patients. The Glaxo trial, unlike the "313" study, had not been rigged to select study centers that had previously shown a high likelihood of success. The disclosure revealed to investors what the defendants had known as a result of their "302" and "313" studies: that Entereg was beneficial as a treatment for POI for only a small subgroup of patients treated at elite medical centers, where the standards of patient care greatly exceeded those typically available. Upon announcement of the failed Glaxo Entereg study, Adolor's stock again plummeted by 46%. The *Adolor* securities litigation ensued, though Adolor and its executives were ultimately successful at getting the charges dismissed under the Private Securities Litigation Reform Act's stringent pleading requirements.

37. Meanwhile, on August 18, 2004, Halsey, now a convicted felon and federal securities law violator, formally changed its name to Acura Pharmaceuticals, Inc. and the Company's publicly traded stock began trading under the ticker symbol "ACUR."

REGULATORY BACKGROUND TO THE CLASS PERIOD

38. On November 13, 2004, Acura announced that it had received regulatory clearance to initiate a clinical trial program for its first oxycodone drug deterrent product candidate ("Product Candidate No. 1") following the acceptance by the FDA of an

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[1] A "refusal to file" an NDA is defined under 21 CFR §314.101. Under this regulation, the FDA has 60 days to make a threshold determination that the application is sufficiently complete to permit a substantive review.

investigational new drug application ("IND") in October 2004. According to defendants, the clinical development program for Product Candidate No. 1 would focus on optimizing the formulation to most effectively deter the potential for abuse while minimizing any new adverse events compared to non-ADF formulated products. According to defendants, in October 2004, after amending such IND, the Company was cleared by the FDA to begin phase I clinical trials for Product Candidate No. 1. Defendants also stated that through the use of a laboratory contract research organization ("CRO"), the Company had evaluated Product Candidate No. 1 in a single dose clinical study to assess the bioavailability and bioequivalence (BA/BE) of such product candidate in comparison to a frequently prescribed, commercially marketed drug product with the same opioid active ingredient, as Acurox but without abuse deterrent properties. Defendants stated the results of the BA/BE study indicated that Product Candidate No. 1 was sufficiently bio-available but not bio-equivalent to the referenced commercially marketed opioid product. The Company had subsequently developed a revised formulation of Product Candidate No. 1 and stated it planned to test the revised formulation in a pilot BA/BE study to confirm that the revised formulation was both bio-available and bio-equivalent to a commercially marketed product without the abuse deterrent properties.

39. On April 16, 2005, Acura announced the initiation of a clinical trial for the Company's "Product Candidate No. 2." Product Candidate No. 2 was an orally administered opioid tablet incorporating the Company's abuse deterrent formulation technology (the "Aversion Technology"). The Aversion Technology was said to incorporate certain opioid active ingredients plus additional ingredients intended to deter the abuse of orally administered opioid products. According to Acura's April 15, 2005 release, the first clinical trial for Product

Candidate No. 2 would assess the tolerability of the proposed commercial formulation in 66 opioid naive subjects.

40. Since February 2006, Acura has referred to itself as a "specialty pharmaceutical company primarily engaged in research, development and manufacture of innovative abuse deterrent, abuse resistant and tamper resistant formulations ('Aversion Technology') intended for use in orally administered opioid-containing pharmaceutical products." The Company's lead product candidate is and has been its Aversion Technology, OxyADFTM tablets ("Acurox", formerly referred to by the Company as Product Candidate No. 2) which it claimed was being developed pursuant to an active investigational new drug application ("IND") on file with the FDA.

41. According to Acura during the Class Period, the misuse and abuse of pharmaceutical products in general, and opioid analgesics in particular, was a significant societal problem described as epidemic in nature. Defendants estimated 75 million people in the U.S. were suffering from pain, and, citing U.S. government surveys, estimated 34.9 million people, ***or more than 10% of the U.S. population***, had used prescription opioid analgesics non-medically at some point in their lifetime.

42. Defendants stated they had contracted, through an independent market research firm, numerous market research studies including two which surveyed 401 and 435 opioid analgesic prescribing U.S. based physicians, respectively. According to defendants, these studies revealed that physicians were keenly aware of opioid analgesic abuse and were personally concerned with the potential impact of drug abuse on their respective medical practices. Acura reported its study of 401 physicians indicated that of the prescriptions likely to be written for the Company's product candidates that utilize the analgesic oxycodone, ***59% would be switched***

from immediate release products containing either hydrocodone or oxycodone, with the remaining 41% being switched from other currently marketed opioid analgesic products such as codeine, propoxyphene, morphine, and tramadol. Defendants stated that ninety-four percent (94%) of 401 physicians surveyed indicated ***they would either prescribe one of the Aversion Technology products profiled in the market research questionnaire for one of their last five patients receiving an opioid prescription or they were aware of a patient in their practice for whom Aversion Technology opioid analgesic products would be an appropriate choice.***

43. By the start of the Class Period, defendants were reporting that Aversion Technology opioid analgesic products, including Acurox, had been evaluated, and were being further evaluated, in numerous well-run, ongoing clinical trials, and that based on what defendants knew then, FDA approval would be forthcoming under FDA Section 502(b)(2) which allows a company combining drugs with known – and tested properties – to forego the more rigorous NDA approval process for unknown substances by simply demonstrating "bioequivalence" to the comparator drug(s).

44. Nonetheless, under governing regulations promulgated by the FDA, companies sponsoring clinical trials, such as Acura, were required to monitor clinical drug trials, review and evaluate evidence relating to the safety and effectiveness of the new drug candidate, and submit annual reports to the FDA regarding the progress of the investigation. In pertinent part, 21 CFR §312.56, "Review of ongoing investigations," provides,

> The sponsor shall monitor the progress of all clinical investigations being conducted under its IND [investigational new drug application].
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> * * *
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> The sponsor shall review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator. The sponsors shall make such reports to [the] FDA regarding information relevant to the safety of the

> drug as are required under 312.32. The sponsor shall make annual reports on the progress of the investigation in accordance with 312.33.

Id.

45. 21 CFR §312.33, "Annual reports" describes the information that sponsor companies are required to submit to the FDA on an annual basis:

> A sponsor shall within 60 days of the anniversary date that the IND went into effect, submit a brief report of the progress of the investigation that includes:
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> (a) Individual study information. A brief summary of the status of each study in progress and each study completed during the previous year. ***The summary is required to include the following information for each study:***
>
> > (1) The title of the study (with any appropriate study identifiers such as protocol number), its purpose, a brief statement identifying the patient population, and a statement as to whether the study is completed.
> >
> > (2) The total number of subjects initially planned for inclusion in the study; the number entered into the study to date, tabulated by age group, gender, and race; the number whose participation in the study was completed as planned; and the number who dropped out of the study for any reason.
> >
> > (3) ***If the study has been completed, or if interim results are known, a brief description of any available study results.***
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> (b) Summary information. Information obtained during the previous year's clinical and nonclinical investigations, including:
>
> > (1) A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system.
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> > (2) A summary of all IND safety reports submitted during the past year.
> >
> > (3) A list of subjects who died during participation in the investigation, with the cause of death for each subject.
> >
> > (4) A list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related.
> >
> > ***(5) A brief description of what, if anything, was obtained that is pertinent to an understanding of the drug's actions, including, for***

> ***example, information about dose response, information from controlled trials, and information about bioavailability.***
>
> (6) A list of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings.
>
> (7) A summary of any significant manufacturing or microbiological changes made during the past year.
>
> (c) A description of the general investigational plan for the coming year to replace that submitted year earlier. The general investigational plan shall contain the information required under 312.23(a)(3)(iv).
>
> (d) If the investigator brochure has been revised, a description of the revision and a copy of the new brochure.
>
> (e) A description of any significant Phase 1 protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.
>
> (f) A brief summary of significant foreign marketing developments with the drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country.
>
> (g) If desired by the sponsor, a log of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment, or meeting.

Id. [Emphasis added.]

46. In compliance with FDA regulations, Acura purported to receive, analyze, and report basic interim data from the Aversion Technology opioid analgesic products, including Acurox, clinical trials to the FDA prior to, and throughout, the Class Period. However, beginning with specific data arising out of the Company's pre-clinical trials and specific negative reactions the FDA expressed concerning the niacin additive and Acura's failure to demonstrate sufficient efficacy to outweigh its side effects at the February 2006 "face-to-face" meeting with Acura, defendants intentionally concealed throughout the Class Period that: (i) the Company's clinical data was incomplete and defective, especially as to demonstrating Acurox's niacin

additive was acceptable to non-abusing patients in need of effective pain relief therapy; (ii) that Acura's clinical studies were defectively designed; (iii) that the Company was ignoring specific directives from the FDA as to specific clinical trials Acura needed to conduct and specific evidence Acura needed to demonstrate deterrence efficacy; (iv) that that no evidence of a deterrence effect had ever been presented to the FDA; and (v) that Acura's own pre-clinical and clinical data demonstrated that any negative deterrent effect of niacin overdosing could be easily eliminated by drug abusers by simply by eating food or taking aspirin. Worse, Acura's flawed clinical trials demonstrated that it was ***non-abusers*** who were most likely to suffer the uncomfortable adverse effects from the niacin, even at the dosing level Acura maintained throughout the Class Period would not result in meaningful adverse side effects to non-abusers.

ACURA'S ACUTE FINANCIAL NEED TO SIGN A THIRD-PARTY LICENSING DEAL AT THE START OF THE CLASS PERIOD

47. At the start of the Class Period, Acura reported that it had "incurred net losses of approximately $12.1 million for the year ended December 31, 2005 and $70.0 million, $48.5 million, and $59.6 million for 2004, 2003, and 2002, respectively," that it had a $2.4+ million working capital deficiency, that Acura had a "negative cash flow," that its accumulated deficit as of December 31, 2005 "was approximately $291.6 million," and that its ability to raise additional capital through debt financing was restricted. The Company's 10-K also disclosed that "***in its report dated February 1, 2006 . . ., [Acura's] registered independent public accounting firm referred to substantial doubt about the Company's ability to continue as a going concern as a result of recurring losses, net capital deficiency and negative cash flows.***"

[Emphasis added.]

48. Defendants also disclosed that a group of investors who then owned approximately 78% of Acura's common stock, and which defendants conceded had sufficient

seats on its Board of Directors and power to control the Company's actions – and that those investors might exercise that power and influence against the interest of Acura's other shareholders – ***had provided a $750,000 bridge loan in January 2006***.[2] This group of investors, led by Care Capital, Essex Woodlands Health Ventures and Galen Partners (the "2004 Lead Investor Group"), had previously provided Acura with a $1+ million bridge loan in November 2005, a $0.5 million bridge loan in September 2005 and a June 2005 bridge loan of $1 million. According to defendants, ***even after these bridge loans***, "[a]s of February 1, 2006, the Company had cash and cash equivalents of [***only***] approximately ***$647,000***" and that the "Company estimates its current cash reserves will be sufficient to fund the development of the Aversion® Technology and related operating expenses ***only through mid-to-late March, 2006."*** According to the Company's 2005 10-K: ***"[t]he Company's future sources of revenue, if any, will be derived from contract signing fees, milestone payments and royalties and/or profit sharing payments from licensees for the Company's Aversion® Technology"*** and ***"[t]o fund further operations and product development activities, the Company must raise additional financing, or enter into alliances or collaboration agreements with third parties."***

[Emphasis added.]

49. The 2004 Lead Investor Group would provide an additional bridge financing during the first 15 months of the Class Period, including: (i) a $750,000 loan announced March 27, 2006, which the Company then disclosed would only provide sufficient operating capital through May 2006; (ii) an $800,000 loan announced May 26, 2006 which the Company then said

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[2] According to the Company's 2005 10-K, this group of investors obtained their 78% ownership through a series of transactions beginning with a February 2004 investment of $12.3 million and ending in September 2005 with the group's preferred stock being converted into over 300 million shares of common stock as a result of Acura's inability to meet required capital levels.

would only provide sufficient operating capital through June 2006; (iii) a $335,000 loan announced June 30, 2006 which the Company said would provide sufficient operating capital through July 2006; (iv) a $450,000 loan announced August 16, 2006 which the Company said would provide sufficient operating capital through September 2006; (v) a $489,000 loan announced September 22, 2006 which the Company then said would only provide sufficient operating capital through mid-October 2006; (vi) a $620,000 loan announced October 20, 2006 which the Company then said would only provide sufficient operating capital through mid-November 2006; (vii) a $534,000 loan announced November 30, 2006 which the Company then said would only provide sufficient operating capital through mid-February 2007; (viii) a $600,000 loan announced April 2, 2007 which the Company then said would only provide sufficient operating capital through May 2007; and (ix) a $600,000 loan announced July 10, 2007 which the Company said would provide sufficient operating capital through July 2007.

50. Thereafter, on August 20, 2007, Acura would disclose that it had entered into a Securities Purchase Agreement with the 2004 Lead Investor Group (and others) whereby the Company would sell over 23.6 million "units" (each comprised of four shares and one warrant) in exchange for additional working capital. Defendants' release stated Acura expected the net cash proceeds after expenses of the transaction to be approximately $14.5 million. On October 1, 2007, the Company registered 355,250,449 shares of the Company's common stock for resale by certain of its stockholders, ***including all 345,649,572 shares owned by the 2004 Lead Investment Group***. Through a series of correspondence between the SEC and the Company dated October 10, 22 and 31, 2007, the SEC stated it was taking the position that Acura was itself an underwriter of the offering in light fact that it had essentially issued stock – which then comprised 90% of its outstanding shares –recently in exchange for capital funds.

51. The 2004 Lead Investor Group had strong incentive to cause Acura to misstate the status of the Acurox clinical studies and the probability of Acura receiving FDA approval in order to keep the Company's stock price inflated during the Class Period. First, though the 2004 Lead Investor Group collectively contributed just over $12 million to purchase the 300+ million shares of Acura common stock in 2004, and the significant majority of the $14.5 million the Company received in the August 2007 financing round, this Acura stock comprised a substantial portion of each 2004 Lead Investor Group member's investment portfolio. As such, keeping Acura's stock price artificially inflated strengthened the group members' own balance sheets and increased their individual borrowing capacity and reduced their costs of obtaining capital. Second, falsifying the Company's future business prospects and specifically concealing the adverse clinical data coming out of the Acurox trials inflated the Company's stock price and permitted defendants to obtain a listing on the Nasdaq Stock Exchange on January 31, 2008 and a coveted listing on the Russell 3000 index in June 2008. Both listings, in turn, increased liquidity in the Company's stock and increased analyst coverage, known positive factors to increasing the market price of a Company's stock. Third, the members of the 2004 Lead Investor Group would cause the Company to register 303,982,907 shares of the 345,649,572 shares of Acura they owned for sale in November 2007, seeking and obtaining acceleration of the effective date of Acura's registration statement on Form S-3 under the Securities Act of 1933 to November 20, 2007. Through this registration statement, the 2004 Lead Investor Group – Acura's controlling shareholder which then owned 88% of its common stock – would be permitted to sell all but 41 million shares they held, which, if exercised, would allow them to reduce their total ownership interest in Acura below 10%. While the total sales, transfers and other monetization of individual group members' holdings during the Class Period is not

publicly available, 2004 Lead Investor Group member Care Capital concedes having sold over $766,000 of Acura stock at inflated prices on the open market during three discreet selling periods during the Class Period in March and May 2009 and March 2010.

ACURA'S SENIOR MANAGEMENTS' INCENTIVE TO SIGN A THIRD-PARTY LICENSING DEAL AT THE START OF THE CLASS PERIOD

52. Reddick's 2003 employment agreement with Acura expressly provided "for an annual base salary of $300,000, plus the payment of annual bonus of up to one hundred percent (100%) of Mr. Reddick's base salary based on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors." According to the Company's 2005 10-K, "[f]or the Company's 2006 fiscal year, the Employment Agreement provides for ***a cash bonus equal to 100% of Mr. Reddick's then current base salary (the "2006 Cash Bonus") upon the Company's receipt of aggregate proceeds of at least $15.0 million on or before March 31, 2007*** from an offering of the Company's equity securities ***and/or from license fees or milestone payments from third-party licensing or similar transactions (subject to the payment of a pro-rata portion of the 2006 Cash Bonus provided the Company receives aggregate gross proceeds from such transactions of at least $11.0 million on or before March 31, 2007)."***

[Emphasis added.]

53. Similarly, Spivey's April 5, 2004 employment agreement provided "for an annual base salary of $260,000, plus the payment of annual bonus of up to one hundred percent (100%) of Dr. Spivey's base salary based on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors." According to the Company's 10-K, "[f]or the Company's 2006 fiscal year, the Employment Agreement provides for ***a cash bonus equal to one hundred percent (100%) of***

Mr. Spivey's then current base salary (the "2006 Cash Bonus") upon the Company's receipt of aggregate proceeds of at least $15.0 million on or before March 31, 2007 from an offering of the Company's equity securities ***and/or from license fees or milestone payments from third-party licensing or similar transactions (subject to the payment of a pro-rata portion of the 2006 Cash Bonus provided the Company receives aggregate gross proceeds from such transactions of at least $11.0 million on or before March 31, 2007)."***

[Emphasis added.]

54. Clemens' 1998 employment agreement also provided "for an annual base salary of $180,000 plus the payment of an annual bonus to be determined based on the satisfaction of such targets, conditions or parameters as may be determined from time to time by the Compensation Committee of the Board of Directors." The Company's 2005 10-K disclosed that "[f]or the Company's 2006 fiscal year, the Employment Agreement provides for ***a cash bonus equal to 100% of Mr. Clemens' then current base salary (the "2006 Cash Bonus") upon the Company's receipt of aggregate proceeds of at least $15.0 million on or before March 31, 2007*** from an offering of the Company's equity securities ***and/or from license fees or milestone payments from third-party licensing or similar transactions (subject to the payment of a pro-rata portion of the 2006 Cash Bonus provided the Company receives aggregate gross proceeds from such transactions of at least $11.0 million on or before March 31, 2007)."***

55. Indeed, on October 31, 2007, defendants would disclose that Acura and King Pharmaceuticals Research and Development, Inc., a subsidiary of King Pharmaceuticals, Inc. ("King"), entered into a license, development and commercialization agreement (the "King License Agreement"). Under the terms of the King License Agreement, King obtained an exclusive license in the United States, Mexico and Canada for Acurox. In addition, the King

License Agreement provided King with an option to license all future opioid analgesic products developed utilizing Acura's Aversion Technology. In exchange, King would make a single upfront cash payment to Acura of ***$30 million*** and, depending on the achievement of certain development and regulatory milestones, King could also make additional cash payments to Acura of up to ***$28 million*** relating to Acurox tablets and similar amounts with respect to each subsequent Aversion Technology product developed under the King License Agreement. ***King would also reimburse Acura for all research and development expenses incurred beginning from September 19, 2007 for Acurox Tablets and all research and development expenses related to future products after King's exercise of its option to an exclusive license for each future product.*** In exchange, King would record net sales of all products and pay Acura a royalty ranging from 5% to 25% based on the level of combined annual net sales for all products subject to the King License Agreement. King also promised to make a one-time cash payment to Acura of $50 million in the first year in which the combined annual net sales of all products exceed $750 million. From the King License Agreement proceeds, Acura would immediately repay a $5 million bridge loan due the 2004 Lead Investment Group.

56. Even though the August 2007 stock unit offering (to the 2004 Lead Investor Group) and the October 2007 signing of the King License Agreement were not achieved prior to March 2007, the Company disclosed in a Form 8-K on December 17, 2007, days after the King License Agreement was signed, that on December 13, 2007, Acura awarded cash bonuses to, and effective January 1, 2008, increased the annual salaries of, defendants (and other Acura executives) as follows:

Name	Title	Annual Salary	Bonus Awarded
Andrew D. Reddick	*President and Chief Executive Officer*	*$365,000 (increased from $300,000)*	*$850,000*
Ron J. Spivey	*Senior Vice President and Chief Scientific Officer*	*$315,000 (increased from $260,000)*	*$650,000*

Name	Title	Annual Salary	Bonus Awarded
Peter A. Clemens	***Senior Vice President and Chief Financial Officer***	***$205,000 (increased from $180,000)***	***$180,000***
James F. Emigh	Vice President Marketing and Administration	$160,000 (increased from $140,000)	$140,000
Robert A. Seiser	Vice President, Controller and Treasurer	$160,000 (increased from $133,000)	$140,000

57. According to the Company's 2008 annual proxy statement, defendants Reddick, Spivey and Clemens were awarded these bonuses "due to, among other reasons, the completion of our Unit Offering and the King Agreement." Meanwhile, for FY 2006, Reddick, Spivey and Clemens, respectively, had received $1.375 million, $1.1 million and $733,000 of stock awards while they readied the Company for the August 2007 unit offering and the October 2007 King License Agreement.

FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

58. At the start of the Class Period on February 21, 2006, Acura issued a release entitled "Acura Pharmaceuticals, Inc. Reports 2005 Financial Results, and Updates OxyADF™ Tablet Development, Commercial Strategy and Cash Reserves – OxyADF™ Tablets Development Update." Concerning the Company's ongoing clinical studies of Acurox and the status of the Company's FDA approval efforts, the February 21, 2006 release stated in relevant part that,

> The Company's lead product candidate, OxyADF™ tablets (formerly referred to by the Company as Product Candidate #2) is an immediate release tablet under development pursuant to an active IND on file with the U.S. Food and Drug Administration ("FDA"). During the first quarter of 2006, as a routine part of the development process for OxyADF™ tablets, at the Company's written request, ***the Company and the FDA convened a face-to-face End of Phase 2 meeting ("EOP2 Meeting") for OxyADF tablets. As part of the EOP2 Meeting, the Company and the FDA discussed, among other things, the laboratory and clinical studies completed by the Company to date relating to OxyADF™ tablets and the remaining laboratory and clinical studies anticipated to be completed prior to the submission of a 505(b)(2) NDA for OxyADF™ tablets.*** The Company believes the guidance provided by FDA at the EOP2 Meeting clarifies

the remaining development requirements relating to the Company's proposed indication ***and contemplated labeling for OxyADF™ tablets. The FDA has confirmed in written correspondence to the Company that OxyADF™ is an appropriate product candidate for submission as a 505(b)(2) NDA.***

To date the Company, in concert with its contract research organizations ("CROs") has completed one phase I clinical study and one phase II clinical study relating to development of OxyADF™ tablets. The results from the phase I clinical study were used, among other things, to guide the formulation of the OxyADF tablets used in the phase II clinical study. ***Results from the phase II clinical study suggest that at the anticipated recommended therapeutic doses in normal subjects, OxyADF tablets will provide a side effects profile similar to the same opioid active ingredient formulated in a tablet without the Company's Aversion® Technology.*** The Company intends to use the data from such clinical studies in its 505(b)(2) NDA submission for OxyADF™ tablets.

The Company, in concert with an independent clinical CRO, has completed a pilot and a pivotal bioequivalence study for OxyADF™ tablets. The pivotal bioequivalence study used tablets from batches manufactured by the Company at a scale of sufficient size to fulfill the FDA's requirements for a 505(b)(2) NDA submission. ***The final report from the CRO for the pivotal bioequivalence study confirms that OxyADF™ tablets are bioequivalent to the applicable reference listed drug.*** The Company intends to use such data in its 505(b)(2) NDA submission for OxyADF™ tablets.

* * * *

Commercial Strategy Update

To generate revenue, the Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license OxyADF™ tablets and other product candidates utilizing the Aversion® Technology and further develop, register and commercialize multiple formulations and strengths of such product candidates. ***The Company expects to receive milestone payments and a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Aversion® Technology. Future revenue, if any, would be derived from licensing fees, milestone payments and a share of profits and/or royalty payments relating to our Partners' sale of products incorporating the Aversion® Technology . . . .***

[Emphasis added.]

59. On February 21, 2006, Acura also filed its annual report on Form 10-K with the SEC for the fiscal year ending December 31, 2005 (the 2005 10-K). In relevant

part, the 2005 10-K made the following misrepresentations concerning the Company's ongoing clinical studies of Acurox and the status of the Company's FDA approval efforts:

- "The Company believes that the internally developed Aversion® Technology ***is applicable to both immediate release and extended release*** orally administered tablets and capsules which are formulated with an opioid analgesic or other potentially abusable orally administered drug, such as an amphetamine, as an active ingredient."

- "***Company research and laboratory experiments to date suggest that the Aversion® Technology may be formulated into an orally administered tablet with the commonly utilized opioid active pharmaceutical ingredients*** and related salts including morphine, codeine, hydrocodone and oxycodone."

- "***The Company believes that the Aversion® Technology will discourage or deter a pre-existing opioid drug abuser***, or a legitimate patient properly using opioid containing analgesics for management of pain, from abusing an orally administered opioid containing product."

- "Provided the Aversion® Technology is appropriately tested and proves successful in clinical trials, . . . ***the Company believes that its Aversion® Technology will discourage or deter the three most commonly utilized routes of opioid abuse***, including (1) intravenous, (2) intranasal/snorting and (3) excess oral consumption of tablets or capsules."

- "The Company ***has clearance from the U.S. Food and Drug Administration ("FDA")*** for testing OxyADF™ tablets in a clinical trial program under an active Investigational New Drug application ("IND")."

- "The FDA has confirmed in writing to the Company that ***OxyADFTM is an appropriate product candidate for submission as a 505(b)(2) NDA***."

- "To date the Company, in concert with its CROs has completed one phase I clinical study and one phase II clinical study relating to development of OxyADF™ tablets. The results from the phase I clinical study were used, among other things, to guide the formulation of the OxyADF tablets used in the phase II clinical study. ***Results from the phase II clinical study suggest that at the anticipated recommended therapeutic doses in normal subjects, OxyADF tablets will provide a side effects profile similar to the same opioid active ingredient formulated in a tablet without the Company's Aversion® Technology.*** The Company, intends

to use the data from such clinical studies in its 505(b)(2) NDA submission for OxyADF™."

- "The Company, in concert with an independent clinical CRO, has completed a pilot and a pivotal bioequivalence study for OxyADF™ tablets. The pivotal bioequivalence study used tablets from batches manufactured by the Company at its Culver, Indiana facility at a scale of sufficient size to fulfill the FDA's requirements for a 505(b)(2) NDA submission. ***The final report from the CRO for the pivotal bioequivalence study confirms that OxyADF™ tablets are bioequivalent to the applicable reference listed drug.*** The Company intends to use such data in its 505(b)(2) NDA submission for OxyADF™."

- "During the first quarter of 2006, as a routine part of the development process for OxyADF™ tablets, at the Company's written request, the Company and the FDA convened a face-to-face End of Phase II meeting (the "EOP2 Meeting") for OxyADF tablets. ***As part of the EOP2 Meeting, the Company and the FDA discussed, among other things, the laboratory and clinical studies completed by the Company to date relating to OxyADF™ tablets and the remaining laboratory and clinical studies anticipated to be completed prior to the submission of a 505(b)(2) NDA for OxyADF™ tablets. The Company believes the guidance provided by FDA at the EOP2 Meeting clarifies the remaining development requirements relating to the Company's proposed indication and contemplated labeling for OxyADF™ tablets***."

- "***There are currently three pathways to obtain FDA approval to commercially market and distribute a new pharmaceutical product in the U.S.:***

  1. New Drug Applications ("NDA"). Unless one of the procedures discussed in paragraph 2 or 3 below is available, a prospective manufacturer must conduct and submit to the FDA complete clinical studies to prove a drug's safety and efficacy, in addition to the bioavailability and/or bioequivalence studies discussed below, and must also submit to the FDA information about manufacturing practices, the chemical make-up of the drug and labeling. ***Some of the products anticipated to be developed by the Company which will incorporate the Opioid Synthesis Technologies and the Aversion® Technology will require an NDA filing . . .***

  2. 505(b)(2) NDA. An alternative NDA procedure is provided by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "1984 Act") whereby the applicant may rely on published literature and more limited testing requirements. This application process is useful when the API is commercially available in an alternative dosage form or

formulation. ***The Company has received written confirmation from the FDA that OxyADFTM tablets, the Company's lead product candidate utilizing the Aversion® Technology, is an appropriate product candidate for submission as a 505(b)(2) NDA.***"

[Emphasis added.]

60. The 2005 10-K was accompanied by certifications signed by defendants Reddick and Clemens which stated:

I, [Andrew D. Reddick, Chief Executive Officer of the Company/ Peter A. Clemens, Chief Financial Officer of the Company], certify that:

1. I have reviewed this annual report on Form 10-K of Acura Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure

controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

61. The Company filed an interim quarterly report on Form 10-Q with the SEC for the 1Q 06 which, addressing the "Status of Development of OxyADF™ Tablets," again stating that ***"[t]he FDA has confirmed that OxyADF™ is an appropriate product candidate for submission as a 505(b)(2) new drug application ("NDA")" and that "[t]he final report from the CRO confirms that OxyADF™ is bioequivalent to the applicable reference listed drug."*** Reddick and Clemens certified the Company's 1Q 06 10Q with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

62. On July 27, 2006 the Company issued a release entitled "Acura Pharmaceuticals, Inc. Announces 2nd Quarter 2006 Financial Results and OxyADF™ Tablet Development Status." With regard to the "OxyADF™ Tablet Development Status" update, the July 27, 2006 release stated that ***"[t]he FDA has confirmed that OxyADF™ is an appropriate product***

candidate for submission as a 505(b)(2) new drug application ("NDA") and have confirmed in writing to the Company that no additional toxicology studies are required prior to submission of such NDA." The July 27, 2006 release also contained a misleadingly veiled discussion of the "flushing" effect experienced as a result of Acurox's niacin additive, but in which defendants: (i) ***continued actively concealing the unacceptably adverse side effects they knew the niacin caused in non-abusers at levels the FDA would find intolerable;*** (ii) ***continued actively concealing that abusers could counteract the flushing affect by ingesting food and/or aspirin;*** and (iii) ***affirmatively misstated the implications they knew the niacin side effects would have on the Company's ability to obtain FDA approval***:

> OxyADF™ contains a second active ingredient in a sub-therapeutic amount. This second active ingredient has a well established side effect profile in long term administration at doses more than ten-fold greater than the amount contained in the proposed maximum recommended daily dose of OxyADF™ tablets. ***When OxyADF™ is administered at the intended recommended dose of 1 or 2 tablets every 4-6 hours, then it is expected that legitimate acute pain patients will not feel the affects this extra active ingredient. However, when either a legitimate acute pain patient or a potential drug abuser consumes excess quantities of OxyADF™ tablets, we anticipate he/she will experience an unpleasant combination of symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort.*** It is expected that these symptoms will begin approximately 10-15 minutes after the excess dose is consumed and self-resolve approximately 75-90 minutes later. The Company does not expect that the undesirable effects from this extra active ingredient will be "fool-proof" in discouraging excess oral consumption of OxyADF™ tablets ***but anticipates that it will cause most patients or potential abusers to experience unpleasant effects if excess quantities of OxyADF™ are consumed orally.*** As described below, the Company is currently evaluating the effects of this second active ingredient in clinical studies involving subjects with no history of opioid abuse as well as in subjects with a history of opioid abuse.

[Emphasis added].

63. The July 27, 2006 release also advised that the Company had completed patient enrollment in one phase I clinical trial (Study AP-ADF-101), one phase II clinical trial (Study AP-ADF-103), a pivotal bioequivalence trial (Study AP-ADF-104) and a pivotal laboratory

study relating to the development of OxyADF™. According to defendants' July 27, 2006 release, Study AP-ADF-103 demonstrated that "Oxycodone HCl administered four times a day, ***with or without the second active ingredient was determined to be well tolerated***" and that "***[n]o severe adverse events were reported in any treatment group . . .***" As such, the "Company intend[ed] to include the data and results from Study AP-ADF-103 in its 505(b)(2) NDA submission for OxyADF™ to the FDA." According to defendants' July 27, 2006 release, Study AP-ADF-104 "demonstrated that OxyADF™ tablets are bioequivalent to Roxicodone® tablets," the bioequivalent comparator used, and the "90% confidence intervals for peak exposure based on ln(Cmax) and overall systemic exposure based on ln(AUClast) and ln(AUCinf) of oxycodone were well within the FDA's acceptable range for bioequivalence." As such, the "Company intend[ed] to include the data and results of Study AP-ADF-104 in its 505(b)(2) NDA submission for OxyADF™ to the FDA."

[Emphasis added.]

64. The Company's 2Q 06 interim financial report on Form 10Q, filed with the SEC on July 27, 2006 as well, contained the same statements described above in the Company's July 27, 2006 release. Reddick and Clemens certified the Company's 2Q 06 10Q with the same certifications addressed *supra*.

65. On November 3, 2006, the Company filed an interim quarterly report on Form 10-Q with the SEC for the 3Q 06 which, addressing the "Status of Development of OxyADF™ Tablets," again stated that ***"[t]he FDA has confirmed that OxyADF™ is an appropriate product candidate for submission as a 505(b)(2) new drug application ("NDA")"*** and that "[t]he final report from the CRO confirms that OxyADF™ is bioequivalent to the applicable reference listed drug." The 3Q 06 10Q contained the same discussion of the Study AP-ADF-103

and the Study AP-ADF-104 described *supra* at ¶63. The 3Q 06 10Q again falsely reported that based on the Company's clinical findings, "[w]hen OxyADF Tablets are administered at the intended recommended dose of 1 or 2 tablets every 4-6 hours, ***it [was] expected that legitimate acute pain patients w[ould] not feel the affects of this extra active ingredient***," referring to the niacin additive without naming it accurately disclosing the level of side effects defendants then knew was unacceptable to the FDA. The 3Q 06 10Q also again falsely stated that based on what defendants knew then, the Company "***anticipate[d] that it w[ould] cause most people to experience unpleasant effects if excess quantities of OxyADF Tablets are consumed orally***." Reddick and Clemens certified the Company's 3Q 06 10Q with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

66. On March 15, 2007, the Company issued a release entitled "Acura Pharmaceuticals, Inc. Updates OxyADF Tablets – Development Program and Results of Study AP-ADF-102." Significantly, the Company's March 15, 2007 release expressly disclosed (or appears to be the first time) that Acurox contained niacin. ***However, the March 15, 2007 release misleadingly downplayed the importance of the disclosure by stating the "conclusion from Study 102 supports the hypothesis that the addition of niacin to oxycodone in a minimal ratio of 30 mg niacin to 5 mg oxycodone is aversive when compared to oxycodone alone and the addition of niacin to oxycodone does not alter the safety profile of oxycodone alone in subjects with a history of opioid abuse.***" Indeed, the March 15, 2007 release stated the "Company intends to include the data and results from Study-102 in its 505(b)(2) NDA submission for OxyADF Tablets." Moreover, ***for what appears to be the first time***, the March 15, 2007 release disclosed that Study AP-ADF-101 was expressly designed to "[e]valuate optimal amount of

niacin per tablet," stating the "[f]inal study report [was] complete" – but not disclosing what had prompted the FDA to require the testing. The March 15, 2007 release also misleadingly stated that the "[f]inal study report" for Study 104 was "complete" and had demonstrated that "OxyADF tablets are bioequivalent to reference listed drug." The March 15, 2007 release also stated the "[f]inal study report" for Study 103, "[r]epeat dose safety and tolerability study in normal subjects," was "complete," without disclosing the basis of the results. Finally, the March 15, 2007 release disclosed as to the status of Study "107 Niacin dose-response safety and tolerability in normal subjects," that the "[s]ubject enrollment [was] complete," that a "[s]ummary study report [was] complete" and that a "[f]inal study report [was] drafted." [Emphasis added.]

67. On March 15, 2007 the Company filed its annual financial report on Form 10-K for Fiscal 2006 with the SEC. In addition to reiterating the false and misleading statements described from the Company's March 15, 2007 release, the 2006 10-K made the following misrepresentations concerning the ability of Acurox to deter drug abuse and the extent to which the FDA would allow Acura to label Acurox as an abuse deterrent:

> ***. . . we anticipate that inclusion of niacin in OxyADF Tablets and other Aversion® Technology product candidates will deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of OxyADF Tablets. We anticipate that most potential drug abusers or recreational drug users will seek alternative opioid analgesic products that are generally much easier to abuse than OxyADF Tablets, and do not have the potential to cause these undesirable niacin effects . . . .***
>
> * * * *
>
> ***. . . The FDA . . . also provided written guidance to the Company stating that language regarding abuse deterrence, which is supported by rigorous, scientific data, may be placed into appropriate sections of the OxyADF Tablet product label. In this regard, the Company intends to seek FDA approval of language in the OxyADF Tablet product label describing the physical characteristics of the product and likely results if attempts are made to dissolve tablets in solvents***

> ***for intravenous injection, and/or snort crushed tablets, and/or swallow excessive numbers of tablets. The Company believes this product labeling strategy will provide a viable promotional platform for the commercialization of OxyADF Tablets and other product candidates utilizing Aversion® Technology*** . . . .

[Emphasis added.]

68. Reddick and Clemens certified the Company's 2006 10-K with the same certifications addressed *supra* at ¶60.

69. On May 4, 2007, the Company filed an interim quarterly report on Form 10-Q with the SEC for the 1Q 07 which again stated "OxyADF Tablets ... [were] being developed pursuant to an active investigational new drug application ("IND") on file with the FDA" and that ***the "FDA ha[d] provided written guidance to the Company stating that OxyADF Tablets [were] an appropriate product candidate for submission as a 505(b)(2) NDA*** and ha[d] confirmed in writing to the Company that no additional toxicology studies [were] required prior to submission of such NDA." Like they had in the 2006 10-K, defendants stated in the 1Q 07 10Q that "when a person swallows excess quantities of OxyADF Tablets, it is intended that they will experience an unpleasant combination of symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort," and that based on what they knew then, ***defendants "anticipate[d] that inclusion of niacin in OxyADF Tablets and other Aversion® Technology product candidates [would] deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of OxyADF Tablets" such that "most potential drug abusers or recreational drug users w[ould] seek alternative opioid analgesic products that [were] generally much easier to abuse than OxyADF Tablets, and do not have the potential to cause these undesirable niacin effects."*** Concerning the status of FDA labeling discussions ***and thus commercial marketability of Acurox***, the 1Q 07 10Q stated "[t]he FDA [had] provided written guidance to the Company stating that ***language***

regarding abuse deterrence, which is supported by rigorous, scientific data, may be placed into appropriate sections of the OxyADF Tablet product label," that "[i]n this regard, the Company intend[ed] to seek FDA approval of language in the OxyADF Tablet product label describing the physical characteristics of the product and likely results if attempts [were] made to dissolve tablets in solvents for intravenous injection, and/or snort crushed tablets, and/or swallow excessive numbers of tablets," ***and that the "[t]he Company believe[d] this product labeling strategy w[ould] provide a viable promotional platform for the commercialization of OxyADF Tablets and other product candidates utilizing Aversion® Technology."*** Reddick and Clemens certified the Company's 1Q 07 10Q with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

70. On June 19, 2007, defendants issued a release entitled "Acura Pharmaceuticals, Inc. and FDA Reach Agreement on Special Protocol – Assessment for Pivotal Phase 3 Study for OxyADF Tablets," which stated in relevant part that "[a] SPA is a process in which the FDA provides evaluation and guidance on protocols for Phase 3 clinical trials." The release stated the ***"FDA's agreement to the SPA confirms that the design, primary endpoint, and planned statistical analyses of the study adequately addresses the requirements supporting a New Drug Application (NDA) submission for OxyADF Tablets"*** and that the "FDA previously communicated to the Company that only one successful Phase 3 pivotal study will be required prior to NDA submission."

[Emphasis added.]

71. On August 9, 2007, the Company filed an interim quarterly report on Form 10-Q with the SEC for the 2Q 07 which again stated "OxyADF Tablets [were] being developed pursuant to an active investigational new drug application ("IND") on file with the FDA" and

that ***the "FDA ha[d] provided written guidance to the Company stating that OxyADF Tablets [were] an appropriate product candidate for submission as a 505(b)(2) NDA*** and ha[d] confirmed in writing to the Company that no additional toxicology studies [were] required prior to submission of such NDA." Like they had in the 1Q 07 10Q, defendants stated in the 2Q 07 10Q that "when a person swallows excess quantities of OxyADF Tablets, it is intended that they will experience an unpleasant combination of symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort," and ***that defendants "anticipate[d] that inclusion of niacin in OxyADF Tablets and other Aversion® Technology product candidates [would] deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of OxyADF Tablets" such that "most potential drug abusers or recreational drug users w[ould] seek alternative opioid analgesic products that [were] generally much easier to abuse than OxyADF Tablets, and do not have the potential to cause these undesirable niacin effects."*** Concerning the status of FDA labeling discussions ***and thus commercial marketability of Acurox***, the 2Q 07 10Q stated "[t]he FDA [had] provided written guidance to the Company stating that ***language regarding abuse deterrence, which is supported by rigorous, scientific data, may be placed into appropriate sections of the OxyADF Tablet product label***," that "[i]n this regard, the Company intend[ed] to seek FDA approval of language in the OxyADF Tablet product label describing the physical characteristics of the product and likely results if attempts [were] made to dissolve tablets in solvents for intravenous injection, and/or snort crushed tablets, and/or swallow excessive numbers of tablets," and that ***the "[t]he Company believe[d] this product labeling strategy w[ould] provide a viable promotional platform for the commercialization of OxyADF Tablets and other product candidates utilizing Aversion® Technology."*** Once again, Reddick and

Clemens certified the Company's 2Q 07 10Q with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

72. On October 31, 2007 defendants issued a release disclosing entry into the King License Agreement. The release quoted Reddick expressly stating that while the commercialization of Acurox would "benefit[] patients, healthcare providers, third party payors, and society as a whole," defendants then ***"expect[ed] to create substantial value for King and Acura shareholders***."

[Emphasis added.]

73. On November 2, 2007, the Company issued its 3Q 07 earnings release and filed an interim quarterly report on Form 10-Q with the SEC for the 3Q 07 which again stated "OxyADF Tablets [were] being developed pursuant to an active investigational new drug application ("IND") on file with the FDA" and that ***the FDA had provided written guidance to the Company stating that Acurox Tablets were an appropriate product candidate for submission as a 505(b)(2) NDA*** and had confirmed in writing to the Company that no additional toxicology studies were required prior to submission of such NDA. Like they had in the 2Q 07 10Q, defendants stated in the 2Q 07 10Q that "when a person swallows excess quantities of OxyADF Tablets, it is intended that they will experience an unpleasant combination of symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort," and that based on what they knew then, ***defendants "anticipate[d] that inclusion of niacin in OxyADF Tablets and other Aversion® Technology product candidates [would] deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of OxyADF Tablets" such that "most potential drug abusers or***

recreational drug users w[ould] seek alternative opioid analgesic products that [were] generally much easier to abuse than OxyADF Tablets, and do not have the potential to cause these undesirable niacin effects." Concerning the status of FDA labeling discussions ***and thus commercial marketability of Acurox***, the 2Q 07 10Q stated "[t]he FDA [had] provided written guidance to the Company stating that ***language regarding abuse deterrence, which is supported by rigorous, scientific data, may be placed into appropriate sections of the OxyADF Tablet product label***," that "[i]n this regard, the Company intend[ed] to seek FDA approval of language in the OxyADF Tablet product label describing the physical characteristics of the product and likely results if attempts [were] made to dissolve tablets in solvents for intravenous injection, and/or snort crushed tablets, and/or swallow excessive numbers of tablets," ***and that the "[t]he Company believe[d] this product labeling strategy w[ould] provide a viable promotional platform for the commercialization of OxyADF Tablets and other product candidates utilizing Aversion® Technology."*** Reddick and Clemens certified the Company's 3Q 07 10Q with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

74. On December 10, 2007, defendants issued a release entitled "Acura Pharmaceuticals, Inc. Announces Receipt of $30 Million Cash Payment and Closing of Agreement with King Pharmaceuticals." The release stated in relevant part that as part of signing the King License Agreement that morning, Acura had received "the initial $30 million non-refundable cash payment from King," and that "[u]pon the closing of the Agreement, the Company paid off its $5 million secured term note" to the 2004 Lead Investment Group. In addition to explaining that ***Acura was entitled to receive additional cash payments from King of up to $28 million*** for Acurox Tablets and similar amounts with respect to each future product

licensed based on successful achievement of certain development and regulatory milestones specified in the Agreement, the release expressly explained that going forward, King ***would fund all of Acura's research and development expenses*** and that King would pay Acura "a royalty ranging from 5% to 25% based on the level of combined annual net sales for all products subject to the Agreement." The release also explained that ***"King [would] also make a one-time cash payment to Acura of $50 million in the first year in which the combined annual net sales of all licensed products exceed $750 million."***

[Emphasis added.]

75. On December 10, 2007, Acura filed a Form 8-K with the SEC indicating it had "amended its Code of Ethics to apply to all employees," explaining that "[p]reviously the policy had applied [only to [it's] principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions." Acura's Code of Ethics expressly provided, in relevant part, that the "purpose of the Code [was] to ***deter wrongdoing*** and to promote:

> • ***Honest and ethical conduct***, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
>
> • ***Full, fair, accurate, timely, and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission and in other public communications made by the Company***;
>
> • ***Compliance with applicable governmental laws, rules and regulations***;
>
> • ***The prompt internal reporting of violations of the Code to an appropriate person or persons identified in the Code***; and
>
> • ***Accountability for adherence to the Code."***

[Emphasis added.]

76. Acura's Code of Ethics expressly provided that "[a]ll employees are expected to be familiar with the Code and from time to time may be asked to affirm their agreement to adhere to its standards." In a section expressly detailing "Accurate and Timely Periodic Reports" requirements, the Ethics Code stated that the "***Company [was] committed to full, fair, accurate, timely and understandable disclosure in reports and documents that it files with, or submits to, the Securities and Exchange Commission and in other public communications made by the Company"*** and that its designated officers would "ensure that: • ***Reports filed with or submitted to the Securities and Exchange Commission and other public communications contain information that [was] full, fair, accurate, timely and understandable and do not misrepresent or omit material facts***."

[Emphasis added.]

77. On January 31, 2008, defendants disclosed that the NASDAQ Stock Market® ha[d] approved the Company's application to list its common stock on the NASDAQ Capital Market® ("NASDAQ")." According to Reddick, the "new NASDAQ listing [would] provide enhanced liquidity ***and visibility and we are looking forward to attracting research analyst coverage as a result of our listing***."

[Emphasis added.]

78. On March 5, 2008 defendants issued a release of its 4Q 07 financial results which included the following list of "2007 Accomplishments and 2008 Expectations":

> ***Andy Reddick, President and CEO of Acura said "In 2007 several of the key strategic initiatives that we have been focused on for several years resulted in tangible and positive outcomes. We are pleased to report that the Company is steadily advancing toward our goal*** of becoming a leading specialty pharmaceutical company focused on addressing the growing societal problem of prescription drug abuse. 2007 achievements included:
>
> * * * *

- ***June, 2007 – reached agreement with the FDA for a Special Protocol Assessment for the Company's pivotal phase III safety and efficacy clinical study for Acurox™ Tablets, our lead product candidate***

* * * *

- September, 2007 – commenced our pivotal Phase III safety and efficacy study for Acurox™ Tablets

* * * *

- In 2008 we will remain focused on execution of our strategy and among other things ***expect to:***

- Submit an IND to the FDA for our second Aversion® Technology opioid product candidate in the first half of 2008

- ***Report top line results for our Acurox™ Tablet pivotal Phase III safety and efficacy study prior to the end of the third quarter of 2008***

- Submit to the FDA a 505(b)(2) NDA for Acurox™ Tablets prior to the end of 2008"

[Emphasis added.]

79. Also on March 5, 2008, the Company filed its annual financial report on Form 10-K for FY 07 with the SEC. In addition to reiterating the false and misleading statements described from the Company's March 5, 2008 release, and continuing to conceal the adverse clinical data coming out of the clinical trials and the defects in the trial designs, as the "Company Strategy," the 2007 10-K provided that defendants intended "to utilize existing active pharmaceutical ingredients with proven safety and efficacy profiles that have known potential for abuse, and develop new products utilizing our proprietary Aversion® ("abuse deterrent") Technology" and that defendants "believe[d] that in most cases the FDA's 505(b)(2) NDA approval process may be used with these product candidates." The statements that FDA 505(b)(2) NDA approval was possible for Acurox were false and misleading based on what

defendants then knew about defects in the clinical trial design, the serious adverse niacin side effects being experienced by non-abusers and the lack of meaningful deterrent effect being experienced in the clinical trials by abusers.

80. Specifically addressing the niacin in Acurox, the 2007 10-K stated based on what defendants then knew, they "believe[d] that should a person swallow ***excess quantities of Acurox™ Tablets*** they will experience an unpleasant combination of symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort." Defendants also stated that "[w]hen Acurox™ Tablets are administered ***at the anticipated recommended maximum dose*** of 2 tablets every 6 hours it is intended that legitimate pain patients will receive effective analgesic effects ***and not be aware of the potential dysphoric effects of niacin."*** Defendants also stated that based on what they knew then, they "anticipate[d] that inclusion of niacin in Acurox™ Tablets and in other Aversion® Technology product candidates ***[would] deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of Acurox™ Tablets" and that "most potential drug abusers or recreational drug users [would] seek alternative opioid analgesic products that are generally much easier to abuse than Acurox™ Tablets and do not have the potential to cause these undesirable niacin effects."***

[Emphasis added.]

81. The 2007 10-K also stated that ***"[t]he FDA ha[d] confirmed in writing . . . that the proposed NDA would qualify for a Section 505(b)(2) submission."*** As to the status of the Company's NDA, the 2007 10-K stated "[o]n June 19, 2007, we announced that we had reached agreement with the FDA on the SPA for Study AP-ADF-105," that defendants "began enrolling patients in September 2007 with top line results anticipated in the third quarter of 2008," and that

based on what they knew then defendants "expect[ed] to submit a 505(b)(2) NDA for Acurox™ Tablets prior to the end of 2008."

[Emphasis added.]

82. As to product labeling, and thus commercial sales, of Acurox, the 2007 10-K explained that defendants were "seeking an indication for Acurox™ Tablets for treatment of moderate to moderately severe pain" and that ***the "FDA ha[d] provided written guidance . . . stating that language regarding abuse deterrence (as opposed to an indication for abuse deterrence), which is supported by rigorous, scientific data, may be placed into appropriate sections of the Acurox™ Tablet product label."*** Purportedly based on what defendants knew then, the 2007 10-K stated that they "intend[ed] to seek FDA approval of language in the Acurox™ Tablet product label describing the physical characteristics of the product and likely results if attempts are made to . . . swallow excess quantities of tablets" and that ***defendants then "believe[d] this product labeling strategy [would] provide a viable promotional platform for the commercialization of Acurox™ Tablets . . . ."***

[Emphasis added.]

83. Concerning the status of the Company's clinical testing, the 2007 10-K expressly stated that ***only once "Phase II evaluations demonstrate[d] that a dosage range of the product [was] effective and [had] an acceptable safety profile, [were] Phase III trials . . . undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites***." Defendants again stated in the Company's 2007 10-K that ***"[t]he FDA ha[d] provided written guidance to [them] stating that Acurox™ Tablets [was] a suitable product candidate for submission as a 505(b)(2) NDA."***

Reddick and Clemens certified the Company's 2007 10-K with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

84. On April 24, 2008, defendants issued a joint release with King entitled "King Pharmaceuticals and Acura Pharmaceuticals Announce Completion of Patient Enrollment for Pivotal Phase III Clinical Trial Evaluating Acurox™ - Top-line Clinical Trial Results Expected by July 2008 – NDA Submission Expected before end of 2008." In relevant part, the April 24, 2008 release quoted King's Chief Science Officer stating "[t]his development milestone is an important measure of our continued success in advancing exciting projects to further expand our pain management franchise," and stating ***Acura and King then "expect[ed] that ACUROX™ Tablets [would] be the first approved immediate-release opioid analgesic designed to resist or deter common methods of prescription drug abuse."***

[Emphasis added.]

85. On April 30, 2008, defendants filed Acura's 1Q 08 10-Q. Concerning Aversion Technology, the 10-Q stated that based on what defendants knew then, they "believe[d] that should a person swallow ***excess quantities*** of Acurox™ Tablets they [would] experience an unpleasant combination of symptoms, including warmth or flushing . . .," that they "expected that these dysphoric symptoms [would] begin approximately 10-15 minutes after ***the excess dose*** [was] swallowed and self-resolve approximately 75-90 minutes later," that "[w]hen Acurox™ Tablets [were] administered at ***the anticipated recommended maximum dose*** of 2 tablets every 6 hours it [was] intended that legitimate pain patients [would] receive effective analgesic effects ***and not be aware of the potential dysphoric effects of niacin***." The 1Q 08 10-Q also stated that based on what defendants knew then, they "anticipate[d] that inclusion of niacin in Acurox™

Tablets and in other Aversion® Technology product candidates ***[would] deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of Acurox™ Tablets***" and that they "anticipate[d] that most potential drug abusers or recreational drug users ***[would] seek alternative opioid analgesic products that are generally much easier to abuse than Acurox™ Tablets and do not have the potential to cause these undesirable niacin effects***." The Company's 1Q 08 10-Q also stated that "[t]he FDA [had] confirmed in writing to us that the proposed NDA would qualify for a Section 505(b)(2) submission." As to product labeling, and thus commercialization efforts, the 1Q 08 10-Q stated that based on what they knew then, defendants "intend[ed] to seek FDA approval of language in the Acurox™ Tablet product label describing the physical characteristics of the product and likely results if attempts [were] made to . . . swallow excess quantities of tablets" and ***"believe[d] this product labeling strategy [would] provide a viable promotional platform for the commercialization of Acurox™ Tablets and other product candidates utilizing Aversion® Technology."*** Reddick and Clemens certified the Company's 1Q 08 10-Q with the same certifications addressed *supra* at ¶60. [Emphasis added.]

86. On May 27, 2008, Acura and King issued a release entitled "King Pharmaceuticals Exercises Option to License Third Opioid Product Utilizing Acura's Aversion® Technology – Represents Third of Four Immediate-Release Opioid Products Initially Targeted," which quoted Jones as stating that: ***"Achieving the proof of concept milestone associated with this product and King's exercise of their option further demonstrates the applicability of the AVERSION® Technology platform to a wide range of products susceptible to abuse."*** [Emphasis added.]

87. On June 17, 2008, Acura and King issued a release entitled "ACUROX™ Tablets Meet Primary Endpoint in Pivotal Phase III Study – Opioid With a Unique Composition of Ingredients Intended to Deter Common Methods of Prescription Drug Abuse," that stated in relevant part that "[b]oth strengths of Acurox™ Tablets met the primary pain relief endpoint compared to placebo (p=.0001, and p<.0001)." The June 17, 2008 release also quoted Spivey as stating: "[t]he successful achievement of the primary end point in Study 105 adds another important milestone to a growing array of laboratory and clinical studies designed and conducted by Acura in the development of products using our Aversion® Technology" and that "***[a]fter nearly five years of work, we look forward to submitting an Acurox™ NDA to the FDA by the end of this year and have several additional NDA submissions planned over the next few years.***" The release also quoted King's Chief Science Officer as stating: ***"[t]hese solid Phase III results for Acurox™ represent continued progress*** toward our goal to deliver medicines to physicians and patients that effectively manage pain, while addressing the rise in prescription drug abuse" and that "Acurox™ ha[d] the potential to be the first immediate release opioid on the U.S. market that is designed to reduce the risk of misuse and abuse."

[Emphasis added.]

88. On June 30, 2008 defendants disclosed that Acura had received a $5 million milestone payment from King for "meeting the primary endpoint in its pivotal Phase III study." Also on June 20, 2008, defendants issued a release stating that "Russell Investments [had] selected the Company for inclusion in the Russell 3000 Index and the Russell Microcap Index," commenting that Russell "measure the performance of the 3,000 largest U.S. companies . . . while excluding OTC bulletin board securities and pink-sheet stock due to their failure to meet national exchange listing requirements."

89. On October 13, 2008, Acura and King issued a release entitled "Acura Pharmaceuticals and King Pharmaceuticals Announce Positive Top Line Results of Key Clinical Study Assessing Abuse Liability - Acurox™ Tablets Significantly Disliked When Excess Doses Are Swallowed." In relevant part, the October 13, 2008 release stated ***"Study 111 results demonstrate that Acurox™ Tablets are disliked compared to oxycodone HCl tablets alone when excess doses are swallowed" and that "[t]hese results are statistically significant based on the dislike/like scores (p = .033), the primary measure of abuse deterrence potential for the study."***

[Emphasis added.]

90. On October 27, 2008, defendants filed Acura's 3Q 08 10-Q. The 3Q 08 10-Q stated that based on what defendants knew then, ***the "innovative Aversion® Technology platform [had] been successfully utilized in multiple opioid analgesic product candidates in development and supported by laboratory studies and statistically significant and clinically meaningful Phase II and Phase III clinical study results for Acurox™ Tablets . . . ."*** The 3Q 10-Q also stated that "***Acurox™ . . . ha[d] completed its pivotal Phase III clinical trial successfully meeting the primary pain relief endpoints***." Defendants also stated in the 3Q 08 10-Q that the "FDA ha[d] confirmed, in writing to [them], that ***the proposed NDA for Acurox™ would qualify for a Section 505(b)(2) submission"*** and that "[t]his regulatory strategy ha[d] enabled [defendants] to pursue a more rapid development of Acurox™, which presently included[d] only a single Phase III clinical efficacy and safety study, and the ability to reference preclinical and clinical evaluations for currently marketed opioid products." The 3Q 08 10-Q also stated that "Study 105 . . . demonstrated that Acurox™ Tablets provided statistically significant and clinically meaningful pain relief and were generally well tolerated" and that the

Company had "also completed or ha[d] ongoing additional clinical and non-clinical studies ***intended to demonstrate the abuse deterrent features and benefits of Acurox™ Tablets***." As to product labeling, and thus commercialization, the 3Q 08 10-Q stated that based on what defendants knew then, "Acurox™ Tablets [would] have an anticipated indication for relieving moderate to severe pain ***with features and benefits intended to discourage or deter the most common methods of misuse and abuse including....intentional swallowing of excess quantities of tablets***" and that based on what they knew then, defendants ***"intend[ed] to include in the labels of [Acura's] Aversion® Technology product candidates both a physical description of the abuse deterrent characteristics and information from [its] multiple laboratory and clinical studies designed to simulate the relative difficulty of abusing [its] product candidates."*** Reddick and Clemens certified the Company's 3Q 08 10-Q with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

91. On November 5, 2008, the SEC wrote Reddick making specific inquiries concerning the Company's 2007 10-K, including concerning the King License Agreement requesting that Acura provide the "term and termination provisions, including any payments the company would be required to make in the event of termination," and stating that "[w]e note that you have been granted confidential treatment for information related to termination provisions. The request for confidential treatment was granted without a substantive review of the request. ***As we consider term and termination provisions material, this information should be included in the discussion of the agreement.***" Concerning Executive Compensation, the SEC's November 5, 2008 letter "note[d] statement on page 47 that the employment agreements provide for annual bonus payments subject to the satisfaction of targets, conditions and parameters" and

requested that defendants "disclose the bonus targets for 2007," expressly stating "[y]ou have stated that these bonus determinations considered the fact that no bonuses were paid in the years 2004, 2005 and 2006. ***If you considered the achievement of performance targets in any of these years when determining the amount of bonus payments, these targets should also be disclosed.*** The discussion should include goals for the organization as well as goals specific to each officer."

[Emphasis added.]

92. ***Concerning the termination provision in the King License Agreement, the Company's November 19, 2008 letter back to the SEC (and posted to the SEC's website) disclosed for the first time that "King may terminate the King Agreement in its entirety . . . if regulatory approval of the NDA for Acurox® Tablets is not received prior to March 31, 2010."*** Concerning Executive Compensation, the November 19, 2008 letter back to the SEC disclosed that:

> The 2007 salary and bonus performance targets for Messrs. Reddick, Spivey and Clemens consisted of the completion of a private offering of our securities resulting in net proceeds of at least $10.0 million to fund operations, the conversion of our outstanding, short-term bridge loans into equity or long term debt instructions, the repayment of our $5.0 million secured promissory note and the license of product candidates utilizing our Aversion® Technology to a pharmaceutical company partner. Such performance targets were both organization and individual goals. The salary increases and bonus awards for Messrs. Reddick, Spivey and Clemens reflect the achievement of such performance targets.

And that:

> The salary and bonus performance targets in 2007 for Messrs. Emigh and Seiser were the same as those described above for Messrs. Reddick, Spivey and Clemens, and were both organization and individual goals. The salary increases and bonus awards for Messrs. Emigh and Seiser reflect the achievement of such performance targets. Such salary increases were implemented and bonus awards made following the closing of the King Agreement. The salary and bonus performance targets for both Messrs. Emigh and Seiser for 2008 consist of

> advancing our Acurox® Tablets and other products utilizing our Aversion® Technology through proof of concept and clinical development, implementing the King Agreement, licensing of additional products to King through the exercise of King's options under the King Agreement, and licensing products utilizing our Aversion® Technology outside of North America. Such performance targets are both organization and individual goals.

[Emphasis added.]

93. On December 24, 2008 Acura and King issued a joint release stating that "King ha[d] exercised its option to license a fourth immediate release opioid analgesic product candidate utilizing Acura's proprietary Aversion® Technology" and that "[i]n connection with the exercise of its option, King paid Acura an option exercise fee of $3.0 million."

94. On January 2, 2009, Acura and King issued a joint release entitled "New Drug Application Submitted for Acurox® Tablets – ***Opioid Analgesic Product Designed to Deter Prescription Drug Abuse"*** In relevant part, the January 2, 2009 release stated that "[t]he NDA submission for Acurox® Tablets includes ***positive results*** from the following studies and a proposed product label describing these studies . . . a pivotal Phase III clinical efficacy and safety study ***conducted pursuant to an FDA agreed Special Protocol Assessment with statistically significant (p≤0.0001) primary efficacy endpoints*** [and] three clinical studies assessing the abuse-liability potential of Acurox®, ***demonstrating with statistical significance that subjects with a history of opioid abuse disliked Acurox® compared to immediate release oxycodone HCl alone when snorting crushed tablets or swallowing excess numbers of tablets."***

[Emphasis added.]

95. Once again, on January 28, 2009 the Company received an inquiry from the SEC concerning the Company's 2007 10-K. This time the SEC specifically questioned the Company's basis for recognizing revenue under the King License Agreement based on anticipated FDA 505(b)(2) approval of Acurox, stating in relevant part:

> On page 40, under Revenue Recognition and Deferred Program Fee Revenue, you state that you "have assigned a portion of the program fee revenue to each of the product candidates included under the Agreement and recognize the program fee revenue ratably over our estimate of the development period for each of the products under the Agreement with King." You disclose that this development period ends in November 2009. In your Response Letter you state that "With King's oversight, we will conduct all Acurox Tablet development activities through approval of a 505(b)(2) New Drug Application ("NDA") . . . ." ***Please disclose what specific factors you applied in arriving at the November 2009 end of the development period for each product candidate. Include how you are able to determine that the NDA will be approved by that time.*** Describe the nature and extent of your obligations under the agreement after the NDA is approved.

[Emphasis added.]

96. On February 6, 2009, defendants responded to the SEC's January 28, 2009 inquiry concerning its 2007 10-K in a letter posted to the SEC website in relevant part as follows:

> **Response to Comment**
>
> **Please disclose what specific factors you applied in arriving at the November 2009 end of the development period for each product candidate.**
>
> Our Agreement with King includes four distinct products identified as Product A, Product B, Product C and Product D. The Agreement requires that we develop at least three of the four products. Products were assigned a revenue amortization period as follows:
>
> **Product A:** Pursuant to the Agreement, we are responsible for conducting all development for Product A through regulatory approval by the Food and Drug Administration ("FDA") of a NDA for Product A. Upon execution of the Agreement, we assigned $10 million of the upfront $30 million payment to our development efforts for Product A. We had a plan to complete the required testing for Product A and submit an NDA to the FDA by December 2008. Assuming a December 2008 NDA submission and a 10 month FDA review of the NDA pursuant to the Prescription Drug User Fee Act ("PDUFA") we would obtain regulatory approval of the Product A NDA in November 2009 and our development obligations for Product A would end. ***We submitted our NDA for Product A to the FDA as planned in December 2008 and we continue to assume a standard FDA review and maintain the amortization period to end in November 2009.***

Product B: Pursuant to the Agreement, we are responsible for conducting all development for Product B up to an Investigational New Drug (IND) application becoming effective for Product B pursuant to 21 C.F.R. §312.40(b). At execution of the Agreement, we assigned $10 million of the upfront $30 million payment to our development efforts for Product B. We had a plan to complete the necessary testing and to submit an IND for Product B by May 2008. Pursuant to FDA regulation, an IND automatically becomes effective 30 days following submission unless otherwise notified by the FDA. As such, we estimated our amortization of the Product B revenue to end in June 2008. We submitted our IND for Product B to the FDA as planned in May 2008 and it became effective in June 2008. Thus, we completed the amortization of revenue for Product B in June 2008 and ***pursuant to the Agreement, all future development for Product B will be conducted by King Pharmaceuticals***.

Products C and/or D: Pursuant to the Agreement, we are responsible for conducting all development to successfully complete a "Proof of Concept" for Product C and/or Product D. Thus, we assigned the remaining $10 million of the upfront $30 million payment to Product D because our development obligation was to complete a Proof of Concept for either Product C or Product D. Product D was selected because it was less complex and more advanced in development than Product C and therefore, had a higher probability of success. We had a plan to complete the necessary testing to achieve Proof of Concept for Product D by March 2008. As such, we estimated our amortization of the Product D revenue to end in March 2008. We completed Proof of Concept for Product D in March 2008 and submitted the information to King. King subsequently exercised their option to license Product D in May 2008. As such, we completed our amortization of the revenue on Product D in March 2008 and ***pursuant to the Agreement all future development for Product D will be conducted by King Pharmaceuticals***.

Include how you are able to determine that the NDA [for Product A] will be approved by that time.

Under PDUFA, the FDA has a standard statutory review period of 10 months from the submission of an NDA. The FDA has a 90% success rate of completing its NDA review within the statutory timeframes. We have no definitive method of determining the outcome of FDA's review of our Product A NDA submission. However, ***NDA submissions for products similar to Product A often obtain FDA approval within 10 months after NDA submission***.

Describe the nature and extent of your obligations under the agreement after the NDA is approved.

After our development obligations for each Product are completed, King Pharmaceuticals is responsible for conducting all further product development

> ***activities and for manufacturing (or having manufactured), distributing, selling, marketing, invoicing and collections relating to licensed products . . . .***

[Emphasis added.]

97. On February 23, 2009, the SEC advised Acura that based on its submissions, the SEC had "completed [its] review of [Acura's] Form 10-K and ha[d] no further comments at this time."

98. On February 9, 2009, defendants issued a release disclosing Acura's 2008 financial results and filed its annual financial report with the SEC on Form 10-K. Concerning the purportedly then-present status of the clinical trials and NDA for Acurox, the Company's 2008 10-K stated in relevant part that:

> ***Development of Acurox® Tablets . . . is supported by numerous laboratory studies and statistically significant and clinically meaningful Phase II and Phase III study results.***
>
> * * * *
>
> Aversion® Technology opioid product candidates also include niacin, an active ingredient in vitamins, cholesterol reducers and nutritional supplements, ***in amounts determined by us to be well tolerated when our product candidates are administered at recommended doses but which are intended to induce temporary dysphoric effects as increasing numbers of tablets are swallowed above the recommended dose.***
>
> * * * *
>
> ***We believe that should a person swallow excess quantities of tablets utilizing Aversion® Technology they will experience an unpleasant combination of symptoms,*** including warmth or flushing . . . and a general feeling of discomfort ***as a result of the increasing dose of niacin***. It is expected that these niacin-induced dysphoric symptoms will begin approximately 10 to 15 minutes after ***the excess dose*** is swallowed and will dissipate approximately 75 to 90 minutes later . . . . ***We believe the undesirable niacin effects at escalating doses will not prevent, but are expected to deter, swallowing excess quantities of Aversion® Technology product candidates***.

[Emphasis added.]

99. Concerning product licensing, and thus commercialization, the 2008 10-K stated in relevant part that based on what they then knew, defendants "intend[ed] to include in the labels of [Acura's] Aversion® Technology product candidates both a physical description of the abuse deterrent characteristics and information from [its] numerous laboratory and clinical studies designed to simulate the relative difficulty of abusing [its] product candidates."

100. In relevant part, concerning "The FDA Drug Approval Process," the 2008 10-K stated "[t]he FDA ha[d] provided written guidance to [defendants] stating that Acurox® Tablets is a suitable product candidate for submission as a 505(b)(2) NDA."

101. Reddick and Clemens certified the Company's 2008 10-K with the same certifications addressed *supra* at ¶60.

102. On March 3, 2009, Acura and King issued a release entitled "Acurox(r) Tablets New Drug Application Accepted for Filing With a Priority Review Classification" which stated in relevant part that ***"[t]he FDA may grant an NDA a Priority review classification if its assessment of conditions and information available at the time the application is filed indicates the drug product has the potential to provide, among other things, significant improvements compared to marketed products.***" The March 3, 2009 release also stated that ***"[i]f the Acurox® Tablets NDA is ultimately approved by FDA,*** for which no assurances can be provided, ***the Companies believe Acurox® Tablets will be the first approved immediate release opioid analgesic designed to deter the most common methods of opioid misuse and abuse***." Concerning "Expectations for Acurox Tablets Product Labeling," and thus commercialization, the March 3, 2009 release stated that "[t]he Companies ha[d] included in the proposed label in the Acurox® Tablets NDA both a physical description of the abuse deterrent characteristics of Acurox® Tablets ***and information from a number of laboratory and clinical studies designed***

to simulate the relative difficulty of abusing product candidates utilizing Acura's Aversion® Technology."

[Emphasis added.]

103. On March 26, 2009, defendants issued a release advising that Acura had appointed a Vice President of Modified Release Dosage Form Development, specifically highlighting that the candidate "ha[d] been an advisor to the FDA regarding complex product content uniformity issues and over the years been responsible in leadership roles for a wide array of scientific disciplines including product formulation and development, quality assurance and quality control" and that he "and his scientific teams ha[d] been responsible for dozens of US regulatory submissions and subsequent FDA approvals for brand and generic products."

104. On May 1, 2009, defendants issued Acura's 1Q 09 financial results and filed an interim financial report on Form 10-Q. The Company's 1Q 09 10-Q expressly stated that based on what defendants then knew, the Company's "innovative Aversion® Technology platform ***ha[d] been successfully utilized in developing multiple opioid analgesic products candidates***," that "Development of Acurox® (oxycodone HCl/niacin) Tablets ***[was] supported by numerous laboratory studies and statistically significant and clinically meaningful Phase II and Phase III study results***" and that the "[a]dditional product candidates in development ***[were] supported by laboratory and bioequivalence studies***." Reddick and Clemens certified the Company's 1Q 09 10-Q with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

105. On June 23, 2009, defendants issued a release entitled "Acura Pharmaceuticals Receives Preliminary Review Letter From FDA Regarding Acurox®," which stated in relevant part that ***the "FDA stated in the review letter that their comments [were] preliminary, subject to***

change, and [did] not reflect a final decision on the information reviewed or a review of the entire NDA." Specifically, defendants advised that the Company had not been granted the "Priority review classification" on their FDA 505(b)(2) NDA. Expressly continuing to conceal the actual contents of the FDA's June 18, 2009 letter, defendants' June 23, 2009 release obliquely stated that "[b]ased on this review letter, we do not believe Acurox® Tablets will receive NDA approval ***on the PDUFA date***."

[Emphasis added.]

106. On July 2, 2009, Acura and King issued a joint release entitled "Acura and King Receive FDA Complete Response Letter Regarding Acurox®," which stated in relevant part that the FDA's "Complete Response Letter raise[d] issues regarding the potential abuse deterrent benefits of Acurox®." Again concealing the contents of the letter, the July 2, 2009 release promised "Acura and King [were] currently evaluating the FDA's Complete Response Letter, ***and at this stage believe[d] they [could] respond to the issues raised without conducting any additional studies***" and that "[t]he Companies plan to meet with the FDA following submission of their response." These same assurances were provided again in Acura's July 30, 2009 2Q 09 financial release. The Company's 2Q 09 10-Q filed with the SEC on July 30, 2009 also assured that "[t]he CRL [received from the FDA on June 30, 2009] raises issues regarding the potential abuse deterrent benefits of Acurox®" but that defendants "currently evaluating the CRL, ***and at th[a]t stage [still] believe[d] [they] [could] respond to the issues raised without conducting any additional studies***." Reddick and Clemens certified the Company's 2Q 09 10-Q with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

107. On August 6, 2009, defendants issued a release assuring that "Acura . . . [had] submitted a briefing package to the U.S. Food and Drug Administration (FDA) ***addressing the issues raised in the FDA's June 30, 2009 Complete Response Letter ("CRL")*** related to the New Drug Application (NDA) for Acurox® (oxycodone HCl/niacin) Tablets" and that "Acura and King . . . [were] scheduled to meet with the FDA in late third quarter 2009 to discuss the CRL and the briefing package."

[Emphasis added.]

108. On September 3, 2009, Acura and King issued a joint release entitled "Acura Pharmaceuticals and King Pharmaceuticals Provide Update on Acurox® NDA," stating in relevant part "that they met with the U.S. Food and Drug Administration ("FDA") on September 2, 2009 to discuss the FDA's June 30, 2009 Complete Response Letter regarding the New Drug Application for Acurox® (oxycodone HCl and niacin) Tablets CII (NDA)" and that "[t]he FDA and the Companies agreed to take the NDA to an FDA Advisory Committee ***to consider the evidence to support the potential opioid abuse deterrent effects of Acurox® Tablets.***" The September 3, 2009 release expressly assured that ***"[t]he FDA indicated that no new clinical trials are required at this time."***

[Emphasis added.]

109. On October 26, 2009, defendants issued Acura's 3Q 09 financial release again explaining that "[o]n September 2, 2009 we and King met with the FDA and agreed that the data and evidence supporting the Acurox® Tablets NDA would be presented to an FDA Advisory Committee," this time expressly assuring that ***"[a]lthough the FDA stated that no new clinical trials are required at this time, we and King plan to initiate and complete an additional clinical study to further assess the abuse deterrent features of Acurox®.***" The Company's 3Q 09 10Q

filed with the SEC that day confirmed that "on June 30, 2009 we received from the FDA a Complete Response Letter ("CRL") for the Acurox® Tablets NDA," that the "CRL raised issues regarding the potential abuse deterrent benefits of Acurox®," and that "[o]n September 2, 2009 [Acura] and King met with the FDA and agreed that the data and evidence supporting the Acurox® Tablets NDA would be presented to an FDA Advisory Committee," ***again assuring that "[a]lthough the FDA stated that no new Acurox® clinical trials [were] required at th[at] time, [Acura] and King plan[ned] to initiate and complete an additional clinical study to further assess the abuse deterrent features of Acurox®.***" Reddick and Clemens certified the Company's 3Q 09 10-Q with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

110. On March 2, 2010, defendants issued Acura's 4Q 09 and FY 09 financial results and filed their Form 10-K with the SEC. The Company's 2009 10-K stated that "on June 30, 2009 [defendants] received from the FDA a Complete Response Letter ("CRL")" which "raised issues regarding the potential abuse deterrent benefits of Acurox®." The 10-K also stated that "[o]n September 2, 2009 [Acura] and King met with the FDA ***and agreed that the data and evidence supporting the Acurox® Tablets NDA would be presented to an FDA Advisory Committee***." As they had previously, defendants assured that "[a]lthough the FDA stated that no new Acurox® clinical trials are required at this time, ***we and King are conducting an additional clinical study . . . to further support the abuse deterrent features of Acurox®***."

[Emphasis added.]

111. Purportedly based on what defendants then knew, the 2009 10-K stated defendants continued to "believe that [only] should a person swallow ***excess quantities*** of tablets utilizing Aversion® Technology with niacin ***[would] they . . . experience disliking symptoms,***

including intense flushing . . . and a general feeling of discomfort as a result of the increasing dose of niacin," that they then "expected that these niacin-induced disliking symptoms [would] begin approximately 10 to 15 minutes ***after the excess dose is swallowed*** and [would] dissipate approximately 75 to 90 minutes later," and that based on what they then knew ***defendants continued to "believe the undesirable niacin effects at escalating doses [would] not prevent, but [were] expected to deter, swallowing excess quantities of product candidates utilizing Aversion® Technology with niacin***."

[Emphasis added.]

112. Finally, concerning product labeling, and thus commercialization, the 2009 10-K stated that based on what defendants knew then, they continued to "intend to include in the labels of [Acura's] Aversion® Technology product candidates ***both a physical description of the abuse deterrent characteristics and information from [its] numerous laboratory and clinical studies designed to simulate the relative difficulty of abusing [its] product candidates***." Reddick and Clemens certified the Company's 2009 10-K with the same certifications addressed *supra* at ¶60.

[Emphasis added.]

113. On March 8, 2010, Acura and King issued a joint release entitled "Acura Pharmaceuticals and King Pharmaceuticals Announce Positive Top Line Results of a Clinical Study Assessing Relative Abuse Potential," which stated in relevant part that "top-line results from Study AP-ADF-114 ('Study 114') titled 'A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Assess the Relative Abuse Potential of Acurox® (oxycodone HCl and niacin) Tablets in Non-Dependent Recreational Opioid Users'" had "demonstrate[d] that two different potentially abused excess oral doses of Acurox® Tablets [were] significantly disliked compared to equivalent excess oral doses of oxycodone HCl tablets alone (without niacin)."

114. On March 15, 2010, defendants announced that "clinical evaluation [was] ***now allowed*** under an Investigational New Drug application ("IND") filed with the U.S. Food and Drug Administration ("FDA") for a benzodiazepine [tranquilizer] product candidate utilizing [Acura's] Aversion® Technology," stating "[t]he primary active ingredient in this product candidate [was] intended for the treatment of anxiety disorders."

[Emphasis added.]

115. Defendants' March 8th and March 15th releases had their intended effect and as discussed by *EP Vantage* on April 7, 2010, even though the FDA's June 2009 Complete Response Letter "did not require [Acura] to conduct additional trials, in an effort to improve their chances last month the two published a small 47 patient study showing that the drug was more repellent to non-dependent recreation opioid users when taken in excess orally than current generic version of oxycodone." *EP Vantage* emphasized that "[g]iven that Acura cannot at this stage change the formulation of the drug, providing more supporting evidence about the difficulties of abusing the drug was really the only way forward" and that the "study would also mean that Acura [would] be able to make claims on the label about the drug being more resistant to tampering," giving Acurox a competitive advantage. *EP Vantage* also highlighted that ***"[j]udging from Acura's share price rise in recent days, that has seen the stock lead by 13% since Monday to day's early trading figure of $6.38, contributing to a 32% share price rise in the last month alone, investors at least are feeling positive that the drug could make it through this time."***

[Emphasis added.]

DEFENDANTS' STATEMENTS WERE FALSE AND MISLEADING

116. As set forth more fully *supra*, defendants' statements in ¶¶58-115 were materially false and misleading in that:

(a) The Company's clinical data was incomplete and defective, especially as to demonstrating Acurox's niacin level was acceptable to non-abusing patients in need of effective pain relief therapy;

(b) Acura's clinical studies were defectively designed;

(c) The Company was ignoring specific directives from the FDA as to specific clinical trials Acura needed to conduct and specific evidence Acura needed to demonstrate efficacy with regards to Acura's claimed deterrent effect on abusers;

(d) No evidence had ever been presented to the FDA that niacin discouraged abusers from abusing oxycodone;

(e) Instead, Acura's own clinical data had demonstrated that any negative deterrent effects of niacin overdosing could be easily eliminated by drug abusers by simply eating food or taking aspirin; and

(f) Worse, Acura's flawed clinical trials demonstrated that it was non-abusers who were most likely to suffer the adverse effects from the niacin, even at the dosing level Acura had maintained throughout the Class Period would not result in meaningful adverse side effects to non-abusers, actually decreasing the oxycodone's intended therapeutic pain relief effects.

THE TRUTH BEGINS TO COME TO LIGHT

117. On April 16, 2010, defendants disclosed that a joint meeting of the Anesthetic and Life Support Drugs and the Drug Safety and Risk Management Advisory Committees of the FDA (the "FDA Joint Panel") to consider Acura's Acurox NDA would finally be held on April 22, 2010.

118. On April 20, 2010, the FDA posted its briefing materials for the April 22, 2010 meeting to its own website advising overwhelmingly that Acura's Aversion Technology was nowhere near effective enough to warrant approval. For the first time, the market learned – ***from***

the FDA rather than from Acura – that the Company's clinical data was defective, that its clinical studies were not properly designed, that the Company had wholly ignored specific directives from the FDA over the past four years as to specific clinical trials and evidence Acura had to demonstrate, and that no evidence had ever been presented to the FDA that niacin discouraged abusers from abusing oxycodone. Panelists also pointed out that Acura's ***own clinical data had demonstrated all along*** that any negative effects of niacin overdosing could be easily eliminated simply by eating food or taking Aspirin. Worse, the FDA's analysis of Acura's flawed data – combined with clinical evidence the FDA had to obtain from outside Acura's flawed clinical trials – demonstrated that it was non-abusers who were most likely to suffer the adverse effects from the niacin, even at the dosing level Acura had maintained throughout the Class Period would not result in meaningful adverse side effects to non-abusers.

119. Specifically, the FDA's April 20, 2010 "Executive Summary" expressly disclosed that:

(a) Concerning the study's failure to demonstrate that the niacin flushing reaction would not, as defendants had claimed, inordinately subject non-abusers who were already in pain to additional needless discomfort that could contravene the positive benefits of the oxycodone pain reduction therapy, the FDA's Executive Summary concluded that "[w]hile the oxycodone component in Acurox is efficacious, ***the Agency has concerns about the use of niacin. The niacin component, added to deter drug abuse, appears to negatively affect the adverse event profile of this drug. The incidence of flushing in the Acurox clinical development program for subjects taking oxycodone + 60 mg of niacin ranged from 12% to 77% compared to 1.5% with placebo***." Essentially, the FDA found that patients using Acurox in Acura's clinical trials were far more prone to being nauseous and vomiting to the point where they were having to take other drugs to stop the symptoms. Specifically, "antiemetics" are drugs that are used to reduce nausea and vomiting. The FDA found four patients on the placebo took

these drugs while a whopping 135 patients on Acurox had to take these drugs. Acurox as a medication in whole was supposed to relieve pain, yet patients taking the drug were throwing up and feeling nausea, when patients taking regular immediate release oxycodone demonstrated a far better side effect profile.

(b) The FDA also found the niacin contradictions clearly outweighed its benefits. The FDA specifically found the "[a]pplicant failed to justify the inclusion of niacin under the Combination Drug Regulation," for at least the following reasons: (i) "In the fasted state, ***the niacin doses tested were not particularly aversive***"; (ii) "NSAIDs and aspirin ***are known to mitigate niacin-induced flushing***. Whether aspirin or an NSAID would have mitigated the effects of Acurox could have been elucidated in a clinical trial, ***as recommended by the Agency. The Applicant did not include pretreatment with aspirin in abuse liability studies***. In the absence of data to the contrary, ***the logical assumption*** is that pretreatment with cyclo-oxygenase inhibitor would likely blunt any vasodilatory reaction."

(c) Concerning the debilitating effects on non-abusers, the FDA's Executive Summary also expressly disclosed that "[a]lthough flushing has been reported with use of oxycodone, it is an adverse event that is more frequently associated with niacin. ***In the pivotal controlled clinical trial, the Applicant did not include an oxycodone-only arm, so it is difficult to sort out how much of the reports of flushing in the active arms was due to oxycodone or niacin. However, the available evidence supports the conclusion that the high rates of flushing are primarily a consequence of exposure to niacin, not the oxycodone***."

(d) Despite defendants' repeated claims of abuse deterrence efficacy throughout the Class Period, including Acura's express statements that based on the clinical data the Company provided to the FDA, the FDA had stated in writing the drug was approvable under the FDA's 505(b)(2) NDA process and that the FDA had expressly approved in writing the Company's requested product labeling describing the drugs' purported deterrent effect, the FDA's Executive Summary concluded ***"[t]he Agency also has concerns about the ability of niacin to act as a deterrent to abuse.*** To evaluate the dose that would create a deterrent effect of

niacin, the applicant conducted niacin dose-finding studies in healthy volunteers. ***The results suggest that niacin offers little in the way of deterrence to oral abuse as even at high doses of niacin***, the mean scores for niacin tolerability did not approach the most unfavorable score, '[u]npleasant and difficult to tolerate.' These studies also included an evaluation of the effect of food and found that the aversive effects observed in the fasted state were easily mitigated by food." ***Essentially, though the oxycodone was effective at relieving pain, the niacin additive was not effective at deterring abuse.***

(e) Critically, the FDA's Executive Summary also concluded as to Acurox's deterrence efficacy that "[b]ecause it is known that aspirin and non-steroidal agents are able to greatly decrease the flushing reaction associated with niacin . . . ***the Division requested that the applicant conduct a study that assessed the effects of co-administration of aspirin, but this was not done."***

(f) Finally, the FDA said "it is known that the flushing associated with the use of niacin can lessen over time and, in Study 103, subjects appear to have developed tolerance to niacin within 10 days." Essentially, any deterred effect would be short-lived.

[Emphasis added.]

120. As a result of this disclosure, Acura's stock price declined 42.5% in one day, to close at $6.25 in after-hours trading. This decrease in Acura's stock price was a result of the artificial inflation caused by defendants' misleading statements coming out of the stock price.

121. Finally, on April 22, 2010, the FDA Joint Panel voted 19-1 against approving Acurox. Following the meeting, Acura and King issued a joint release entitled "Update on FDA Advisory Committee Meeting for Acurox – Acura Pharmaceuticals and King Pharmaceuticals Provide Update on FDA Advisory Committee Meeting for Acurox®" which finally disclosed that the FDA's "Anesthetic and Life Support Drugs and Drug Safety and Risk Management Committees voted that they do not have enough evidence to support the approval of the New Drug Application (NDA) for Acurox (oxycodone HCl and niacin) Tablets for the treatment of

moderate to severe pain, considering the deterrent effects of niacin as well as the potential deterrent effects of the other features specific to Acurox." Specifically, defendants finally expressly disclosed that ***the "addition of niacin to Acurox was central to the [FDA's] deliberations."***

122. Critically, as reported by *Reuters* after the April 22, 2010 FDA Joint Panel meeting, ***the "FDA had told the company in July 2009 that the agency would not approve the*** drug but agreed to seek input from the advisory panel, a group of outside experts."

[Emphasis added.]

123. As reported by *Bloomberg* after the April 22, 2010 FDA Joint Panel meeting, Jeffrey Kirsch, chairman of the Anesthetic and Life Support Drugs Advisory Committee said before the vote: "What I'm hearing from the committee is that it's probably not appropriate to put the niacin in this product ***because it does not have a definitive advantage, and it has associated side effects***." Panel member Maria Suarez-Almazor was even more blunt stating: ***"I wish that the product didn't have niacin."*** *Bloomberg* also highlighted that it was revealed at the April 22, 2010 FDA Panel meeting that ***FDA had been aggressively prodding Acura to demonstrate deterrence efficacy since at least May 2009***.

[Emphasis added.]

124. As a result of this disclosure, Acura's stock price declined 39%, to $3.20 per share, in the pre-market trading on April 23, 2010. This decrease in Acura's stock price was a result of the artificial inflation caused by defendants' misleading statements coming out of the stock price.

POST CLASS PERIOD INDICIA OF SCIENTER

125. On May 5, 2010, ***less than two weeks after the April 22, 2010 FDA conference,*** King held its own 1Q 2010 earnings conference call. During its call, King's chairman and CEO expressly conceded that defendants had prior knowledge that the niacin side effects were unacceptable:

> . . . As many of you already know, on April 22nd, King, along with our partners at Acura Pharmaceuticals, presented Acurox to an FDA Advisory Committee. You will remember that Acurox is the first short-acting oxycodone product with a formulation approach containing niacin, specifically designed to be aversive in cases of excessive oral consumption.
>
> Acurox also also contains a unique combination of excipients, designed to limit snorting and deter intravenous administration. Clearly the central issue for the committee was niacin and the relative merits of its contribution to the overall formulation. ***Being aware of the challenges of including niacin as a means to deter abuse, as a contingency, we've been working on a formulation of Acurox without niacin*** and this past Monday we announced that we expect to submit an NDA for this product during the first quarter of 2011.

[Emphasis added.]

LOSS CAUSATION/ECONOMIC LOSS

126. During the Class Period, as detailed herein, defendants made false and misleading statements about the Company's financial performance and condition and engaged in a scheme to deceive the market. This artificially inflated Acura's stock price and operated as a fraud or deceit on the Class. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market between April 20, 2010 and April 22, 2010, Acura's stock price plummeted ***nearly 50% on unusually high trading volume,*** from a close of $7.90 per share at the close of trading on April 19, 2010 to close at $4.02 on April 23, 2010, as the prior artificial inflation came out of the stock price. As a result of their purchases of Acura securities during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

[Emphasis added.]

NO SAFE HARBOR

127. Acura's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

128. The defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Acura who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

129. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's securities traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(e) Plaintiff and other members of the Class purchased Acura publicly traded securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

130. At all relevant times, the market for Acura publicly traded securities was efficient for the following reasons, among others:

(a) As a regulated issuer, Acura filed periodic public reports with the SEC; and

(b) Acura regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

CLASS ACTION ALLEGATIONS

131. 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 Acura publicly traded securities during the Class Period (the "Class"). Excluded from the Class are defendants, directors and officers of Acura and their families and affiliates.

132. 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. Acura has over 43.7 million shares of stock outstanding, owned by hundreds of persons.

133. 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 in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether defendants knew or recklessly disregarded that their statements were false and misleading;

(e) whether the prices of Acura securities were artificially inflated; and

(f) the extent of damage sustained by Class members and the appropriate measure of damages.

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

135. 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.

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

COUNT I

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

137. Plaintiff incorporates ¶¶1-136 by reference.

138. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly 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.

139. 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 Acura publicly traded securities during the Class Period.

140. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Acura publicly traded securities. Plaintiff and the Class would not have purchased Acura publicly traded securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

141. 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 Acura publicly traded securities during the Class Period.

COUNT II

For Violations of §20(a) of the 1934 Act Against All Defendants

142. Plaintiff incorporates ¶¶1-141 by reference.

143. The Individual Defendants acted as controlling persons of Acura within the meaning of §20 of the 1934 Act. By virtue of their positions and their power to control public statements about Acura, the Individual Defendants had the power and ability to control the actions of Acura and its employees. Acura controlled the Individual Defendants and its other

officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;

B. Awarding Plaintiff and the members of the Class damages and interest;

C. Awarding Plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: September 10, 2010