UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CHRIS BANG, 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.	CIVIL ACTION NO**.** 1:10-cv-05757-VK **AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

1. This is a federal class action brought by Lead Plaintiffs Glenn Farmer, John E. Clark, Jr., and John R. Sliwa, (the "Acura Shareholder Investors Group" or "Plaintiffs") on behalf of all those who purchased or otherwise acquired Acura Pharmaceuticals, Inc. securities ("Acura" or the "Company") between February 21, 2006, and April 22, 2010, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). Excluded from the Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest. As alleged herein, during the Class Period, Defendants published a series of statements that Defendants knew and/or recklessly disregarded were materially false and misleading, and/or that omitted to reveal material information that was necessary to make those statements, in light of the circumstance under which they were made, not misleading.

2. Plaintiffs allege the following based upon the investigation of Plaintiffs' counsel, which included a review of SEC filings by Acura, regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, media reports about the Company, and discussions with witnesses with knowledge of the allegations herein. Plaintiffs believe that substantial additional evidentiary support will exist for these allegations after a reasonable opportunity for discovery.

OVERVIEW

3. Acura engages in the research, development, and manufacture of pharmaceutical product candidates that utilize Acura's proprietary Aversion and Impede Technologies—products intended to provide abuse-deterrent features and benefits in medications. In particular, products using the Company's Aversion Technology were intended to effectively relieve pain

while simultaneously discouraging three common methods of abuse: 1) intravenous injection of dissolved tablets; 2) nasal snorting of crushed tablets; and 3) intentional swallowing of excess quantities of tablets. In particular, oral abuse is the most common route by which prescription opioids like oxycodone are abused.

4. This litigation stems from Defendants' materially false and misleading statements and omissions made during the Class Period regarding the purported aversive agent (or deterrent) used in its Aversion Technology to dissuade abusers from "swallowing excess quantities of tablets": niacin (a B vitamin), and regarding the Company's lead product candidate during the Class Period, "Acurox," which was a medicine containing the pain reliever oxycodone, combined with Acura's Aversion Technology.

5. Because Acurox contained two active ingredients (niacin, as a part of the Aversion Technology, and oxycodone) it was subject the FDA rule for "Combination Drugs," 21 C.F.R. 300.50(a), which states, in part: "Two or more drugs may be combined in a single dosage form when each component makes a contribution to the claimed effects . . . ." A "[s]pecial case[] of this general rule," falling under 21 C.F.R. 300.50(a)(2), arises "where a component is added . . . [t]o minimize the potential for abuse of the principal active component." Accordingly, to gain FDA approval, Acurox was required to demonstrate that the niacin in its Aversion Technology minimized the potential for the abuse of oxycodone.

6. According to Acura, the addition of niacin was intended to induce an unpleasant flushing (*e.g.*, skin warmth, redness, itching, and/or tingling) if taken in excess of the labeled dose. However, it was known and/or recklessly disregarded by Defendants that using niacin as an oral abuse deterrent would be difficult, if not impossible, for a myriad of reasons, including, for example:

- The negative, deterrent effects of niacin can be diminished or overcome by eating a high-fat or heavy meal.
- Niacin's negative effects can be mitigated by taking aspirin.
- A tolerance to the negative effects of niacin can be built up in a matter of days.
- The level of discomfort associated with the niacin in Acurox was insufficient to dissuade drug abusers from using Acurox.

7. Dr. Kenneth Sommerville, VP of Clinical Development at King Pharmaceuticals, who spoke at an April 22, 2010, joint meeting of the Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee to address the Acurox new drug application ("FDA Joint Panel Meeting")—a meeting at which certain true, adverse facts about Acurox were revealed—acknowledged that that "[t]he literature supports that NSAIDs [non-steroidal anti-inflammatory drugs], such as aspirin, mitigate flushing associated with niacin" and "[t]he vasodilatory effects of niacin are also known to be mitigated by food."

8. Moreover, Defendants also knew and/or recklessly disregarded, but concealed from investors, that even in the unlikely event that they could demonstrate that Acurox had aversive properties, they faced a substantial and material risk that they would be unable to attain FDA approval because non-abusers, taking the recommended doses of Acurox, also experienced the negative side effects associated with niacin. For example, an "Advisory Committee Meeting Background Package" prepared by the FDA Joint Panel in anticipation of the April 22, 2010, meeting and published on the FDA's website on April 20, 2010 (the "FDA Briefing Materials"), analyzed Acura's clinical studies and revealed that, in subjects taking the *proper* dosage of Acurox, 12% to 77% experienced flushing (compared to 1.5% with the placebo), with an additional 3.7% to 4.4% reporting "feeling hot" (compared to 0.7% for the placebo).

9. In addition to niacin's tendency to cause an adverse profile in non-abusing users, Defendants knew and or/ recklessly disregarded that niacin failed to show abuse-deterring

effects. For example, in addressing findings from Acura's own clinical trials and basic medical data on niacin, the FDA Briefing Materials stated:

> **The Agency also has concerns about the ability of niacin to act as a deterrent to abuse. . . The results [of Acura's dose-finding studies] 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 . . . found that the aversive effects . . . were easily mitigated by food**. **Because 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.** Also, 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 with 10 days**.

[Emphasis added.]

10. During the drug approval process for Acurox, which began at least as early as April 2005 when the Company began clinical trials for Acurox (which was then known as "Product Candidate No. 2" and had been submitted to the FDA on an investigational new drug application), Defendants failed overcome the FDA's concerns regarding the use of niacin or justify the use of niacin in their Aversion Technology. Instead, Defendants ignored and/or recklessly disregarded insurmountable obstacles, failed to conduct sufficient types of clinical trials, and even failed to run trials specifically requested by the FDA. Meanwhile, Defendants made materially false and misleading statements to investors regarding the results of Acura's studies and the medical and commercial potential for Acurox.

11. In their Briefing Materials, the FDA Joint Panel noted: "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." Later, the report reiterated, "Had the Applicant included an oxycodone-only arm. . . the flushing results would be more interpretable. Because those data are lacking, additional sources of information were considered." In other words, Acura's inadequate clinical testing left the FDA to do its own

analysis to demonstrate the drug's failures.

12. Moreover, during the Acurox approval process, the FDA had specifically advised Defendants that they should run an aspirin trial to determine how aspirin might negate the negative side effects of the niacin. Defendants failed to do so because they knew the data would show that aspirin mitigated the oral abuse aspect of their purported "Aversion Technology," and would preclude Acura from getting FDA approval or receiving approval to label their product as an abuse deterrent. Meanwhile, Defendants repeatedly and misleadingly conveyed to investors throughout the Class Period that the FDA was not requiring additional clinical trials.

13. In addition, Defendants represented that their studies showed that the side effects of Acurox were similar to that of oxycodone alone, when, in truth, their studies showed that negative side effects—uncommon to those experienced when taking oxycodone alone—occurred at the recommended does of Acurox. Defendants also represented that Acurox's Aversion Technology had an oral abuse deterring effect, when in truth, the deterrent effect could be mitigated by various means, and was not significantly "disliked" by abusers to be considered aversive.

14. Confidential Witness ("CW") 1, who worked at Acura in various roles for nearly 10 years, including as a scientist, stated that s/he felt compelled to speak with plaintiff's investigators because s/he was aware of "the plan" Acura had for Acurox with niacin and it "did not sit well" with him/her.

15. CW1 reported that s/he and the other scientists/chemists working with Chief Scientific Officer Ron Spivey brought concerns directly to Spivey's attention early on in the development of Acurox. Specifically, CW1 reported that they expressed concerns to Spivey about the niacin and about the testing issues associated with having two active ingredients in

Acurox. According to CW1, Spivey relied on the fact that niacin appeared on the FDA GRAS (generally recognized as safe) list. However, CW1 and the other scientists believed that, even though niacin was recognized as safe, a concern still existed because of the amount of niacin being used, and the fact that it was included in Acurox as an active ingredient. (Specifically, CW1 and the other scientists believed compounds appearing on the GRAS list were generally considered safe only as inert, rather than active, ingredients). In addition, CW1 and his/her team also thought that having two active ingredients would be problematic when trying to identify which active ingredient caused any resulting side effects. CW1 reiterated several times that despite these warnings, Spivey made the decision to use niacin and to pursue the new drug application ("NDA") with the niacin form of Acurox.

16. CW1 also reported that, of the team of approximately six chemists or scientists responsible for manufacturing Acurox, at least three were laid off in 2005 (Charles Frances, Igor Lithotvorik, and Joseph Likowski) and one (Chris Kahaldahl) also left or was fired shortly after. CW1 believed that Chief Scientific Officer Spivey was dismissing people who challenged him or his ideas.

17. In addition to the results of Acura's own studies, the FDA itself had directly informed Acura of its concerns regarding Acurox's niacin component at numerous times during the Class Period. CW2 worked on the Acurox NDA at Premier Research, the contract research organization ("CRO") hired by Acura to assist with compiling the Acurox NDA. CW1 explained that there were two known issues with Acurox: the flushing side effects and the ability to mask the side effects by eating or taking aspirin. CW2 reported that after the NDA was filed (in or about January 2009), and about a month before the Company received a June 30, 2009 Complete Response Letter, Premier received a Discipline Review Letter from the FDA. CW2 explained

that Discipline Review Letters are sometimes produced by the FDA at certain points in the NDA review process. According to CW2, the letter was sent from the FDA clinical team that reviewed the Acurox NDA. CW2 stated that the letter expressed concerns about the high percentage of flushing side effects, and used the word "toxic" to describe Acurox in light of the high instance of non-abusers who were subject to flushing, especially as compared to how easily abusers could avoid the side effects. CW2 confirmed that Premier forwarded all correspondence, including this letter, to Acura executives, including Company Chief Scientific Officer Spivey and/or Defendant Reddick.

18. CW2 stated that the Discipline Review Letter was generally **considered an indication that the drug was unlikely to be approved at all**.

19. Indeed, on June 23, 2009, Defendants announced the receipt of a June 18, 2009, "Preliminary Review Letter" from the FDA. Although Defendants revealed only that "[b]ased on this review letter, we do not believe Acurox Tablets will receive NDA approval on the" date originally expected, and even though they reassured investors that the "FDA stated in the review letter that their comments are preliminary, subject to change, and do not reflect a final decision on the information reviewed or a review of the entire NDA," the market reacted to the revelation regarding the previously undisclosed deficiencies associated with Acurox.

20. On this partial disclosure, Acura stock dropped over 22%, from a closing price of $7.57 on June 22, 2009, to close at $5.89 on June 23, 2009.

21. As a result of this Discipline Review Letter, CW2 stated that the Complete Response Letter received by the Company approximately a month later, on June 30, 2009, was not considered surprising.

22. On July 2, 2009, the Company acknowledged receiving this Complete Response Letter regarding Acurox from the FDA. According to the FDA's website: "A complete response letter provides a more consistent and neutral mechanism to convey that our initial review of an application is complete and **we cannot approve the application in its present form.**" However, Defendants took **no steps to inform investors that a complete response letter meant that the FDA would not approve Acurox** in its current form; instead, Defendants were dismissive of the letter, making no mention of its impact or consequence, stating only: "The Complete Response Letter raises issues regarding the potential abuse deterrent benefits of Acurox. Acura and King are currently evaluating the FDA's Complete Response Letter, and at this stage believe they can respond to the issues raised without conducting any additional studies. The Companies plan to meet with the FDA following submission of their response."

23. In truth, as revealed by the briefing information prepared by the Company in anticipation of the FDA Joint Panel Meeting: "the FDA's only safety issue expressed in the [] Complete Response Letter," and thus **basis for denying the NDA**, was the "occurrence of mild to moderate flushing, ascribed to niacin and reported by some patients in clinical trials, following exposure to the proposed recommended doses of Acurox Tablets." The Company noted: "In the Complete Response Letter the Agency also noted the potential impact of food and NSAIDs on mitigating the disliking effects of niacin. . . ."

24. CW2 reported that several individuals at Acura, King Pharmaceuticals, and Premier Research Group received the FDA's review and complete response letters during the Class Period and also participated in an August 2008 pre-NDA meeting and a September 2009 meeting with the FDA. According to CW2's recollection, these individuals included, among others, from Acura Pharmaceuticals: Defendant Reddick and Chief Scientific Officer Spivey;

from King Pharmaceuticals: Chief Medical Officer Eric Carter and VP of Clinical Development Kenneth Sommerville; from Premier Research Group: James Ottinger, VP Compliance; Bruce Bennett, the FDA's contact at Premier for issues concerning Acurox; Daniel Solorio, Premier's Project Manager for Acurox clinical studies; and James Johnson, Premier's Director of Global Biostatistics.

25. By misrepresenting Acurox's potential for obtaining FDA approval, during the Class Period, Acura obtained a lucrative third-party license with agreement with King Pharmaceuticals that allowed the Company 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 securities held by the Company's venture capital financiers—substantial majority controlling shareholders—was artificially inflated both by the Defendants' false and misleading statements and omissions, and by the Nasdaq and Russell stock listings, increasing the reported value of these investors' holdings during the Class Period, and thus strengthening their own balance sheets.

26. However, when the FDA's decision to reject the Company's Acurox NDA by a vote of 19-to-1 was finally disclosed to the market between April 20, 2010, and April 22, 2010, the Company's stock price plummeted. Over the course of two disclosures revealing that Acurox would not deter oral oxycodone abuse but, to the contrary, would negatively affect the adverse event profile of this drug at recommended doses, and disclosure that the FDA would neither

approve labeling regarding Acurox's deterrent effect or approve the drug at all, Acura's stock price fell over 46%, from a closing price of $7.90 on April 19, 2010, to close at $4.02 on April 23, 2010.

JURISDICTION AND VENUE

27. Jurisdiction is conferred by Section 27 of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §78aa; and 28 U.S.C. §1331. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the SEC [17 C.F.R. §240.10b-5].

28. Venue is proper in this District pursuant to Section 27 of the Exchange Act [15 U.S.C. §78aa]; and 28 U.S.C. §§1391(b) and 1337. Defendant Acura maintains its principal place of business within this District, and/or the individual Defendants conduct business in and many of the acts giving rise to the violations complained of herein took place in this District.

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

PARTIES

30. Lead Plaintiffs Acura Shareholder Investors Group, consisting of Glenn Farmer, John E. Clark, Jr., and John R. Sliwa, purchased the common stock of Acura at artificially inflated prices during the Class Period, as set forth in their previously-filed certifications, incorporated by reference herein, and have been damaged thereby.

Company Defendant

31. Defendant **Acura** is a specialty pharmaceutical researcher and manufacturer. Acura was founded in 1935 and is based in Palatine, Illinois. Acura's stock traded on the Over the Counter Bulletin Board (OTC BB) until it was listed on that Nasdaq Stock exchange in February 2008, where it began trading and continues to trade under the stock symbol ACUR.

Individual Defendants

32. Defendant **Andrew D. Reddick** is and was, during the Class Period, President, Chief Executive Officer, and a Director of the Company. During the Class Period, defendant Reddick signed and certified the Company's Class Period SEC filings, including, but not limited to, Acura's Form(s) 10-Q and 10-K and Sarbanes-Oxley certifications.

33. Defendant **Peter A. Clemens** is and was, during the Class Period, Senior Vice President, Chief Financial Officer, Secretary, and a Director of the Company. During the Class Period, defendant Clemens signed and certified the Company's Class Period SEC filings, including, but not limited to, Acura's Form(s) 10-Q and 10-K and Sarbanes-Oxley certifications.

34. Defendant **Bruce F. Wesson** is and was, during the Class Period, a Director of the Company. During the Class Period, defendant Wesson signed the Company's Class Period SEC filings, including, but not limited to, Acura's Form(s) 10-Q and 10-K. Defendant Wesson also serves on the Company's Compensation Committee.

35. Defendant **William A. Sumner** is and was, during the Class Period, a Director of the Company. During the Class Period, defendant Sumner signed the Company's Class Period SEC filings, including, but not limited to, Acura's Form(s) 10-Q and 10-K. Defendant Sumner also serves on the Company's Audit Committee.

36. Defendant **Immanuel Thangaraj** is and was, during the Class Period, a Director of the Company. During the Class Period, defendant Thangaraj signed the Company's Class

Period SEC filings, including, but not limited to, Acura's Form(s) 10-Q and 10-K. Defendant Thangaraj also serves on the Company's Compensation Committee.

MATERIALLY FALSE AND/OR MISLEADING STATEMENTS AND OMISSIONS MADE BY DEFENDANTS DURING THE CLASS PERIOD

37. 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." Also that day, Acura filed with the SEC its annual report on Form 10-K for the fiscal year ending December 31, 2005. Concerning the Company's ongoing clinical studies of Acurox (then called "OxyADF") and the status of the Company's FDA approval efforts, the February 21, 2006, release and 2005 Form 10-K stated in relevant part that:

> 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.

[Emphasis Added.]

38. These statements were materially false and misleading when made because Defendants knew and/or recklessly disregarded, but failed to disclose, that the Company's "phase II clinical study" had not actually "suggest[ed] that the anticipated recommended therapeutic dose in normal subjects . . . [would] provide a side effects profile similar to the same opioid active ingredient formulated in a tablet without the Company's Aversion Technology." In truth, this study, Study AP-ADF-103 ("Study 103"), had demonstrated that OxyADF/Acurox tablets did not have a side effect profile "similar to the same opioid active ingredient formulated

in a tablet without the Company's Aversion Technology," but instead demonstrated that: 1) flushing actually increased with the dose of niacin; and 2) flushing appeared in as many of 41% of patients taking the recommended dose of OxyADF/Acurox (*i.e.*, non-abusers).

39. The 2005 10-K also 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 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."**

- "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**."

[Emphasis added.]

40. These statements were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that the Company's preliminary clinical trials had already revealed that its "Aversion Technology" would *not* "discourage or deter a pre-existing opioid drug abuser . . . from abusing an orally administered opioid containing product" through "excess oral consumption of tablets or capsules." Instead, its first Phase II study had

already demonstrated that a tolerance to niacin could be built up in just 10 days, and it was well known in the medical industry that niacin's side effects could be mitigated through the consumption aspirin or other NSAIDs or eating a high fat meal.

41. Moreover, Defendants also knew and/or recklessly disregarded that Acura's "phase II clinical study" did *not* "suggest that at the anticipated recommended therapeutic doses . . . [of] 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." In truth, the phase II study revealed a high rate of discomfort and flushing side effects even at recommended doses.

42. As was undisclosed to investors but known and/or recklessly disregarded by Defendants, Acura's clinical studies were defectively designed and, as a result, the Company's clinical data was incomplete and deceptive. In particular, Defendants failed to incorporate studies that would clearly show: whether Acurox's niacin level was acceptable in non-abusing patients in need of effective pain relief therapy; which of Acurox's two active ingredients caused the negative side effects associated with the medication; whether abusers could easily mitigate Acurox's aversive side effects; and whether potential abusers showed a sufficient "dislike" for the drug's side effects that Acurox could be marketed as an abuse deterrent.

43. During the Class Period, Defendants knew and/or recklessly disregarded that they had not presented—and could not ever present—any evidence to the FDA that niacin prevented drug abusers from orally abusing oxycodone.

Materially False and Misleading Statements and Omissions Regarding the Efficacy of and Side Effects Associated with Acura's Aversion Technology

44. Defendants continued, throughout the Class Period, to make materially false and misleading statements regarding the efficacy of the Aversion Technology's deterrent effects as

well as statements concealing the high occurrence of adverse side effects in patients taking recommended doses of Acurox.

45. On July 27, 2006, the Company issued a release entitled "Acura Pharmaceuticals, Inc. Announces 2nd Quarter 2006 Financial Results and OxyADF™ Tablet Development Status." Also, on November 3, 2006, the Company filed with the SEC an interim quarterly report on Form 10-Q for the 3Q:06 which addressed the "Status of Development of OxyADF™ Tablets." The July 27, 2006, release and the Company's November 3, 2006, Form 10-Q both stated:

> 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, [] it is expected that legitimate acute pain patients will not feel the affects of 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].

46. Similarly, the Company's March 15, 2007, Form 10-K for 2006, and its May 4, August 9, and November 2, 2007, Forms 10-Q for the first, second, and third quarters of 2007, respectively, each made the following misrepresentation concerning the ability of Acurox to deter drug abuse:

> [N]iacin, when administered orally in immediate release tablets in amounts **exceeding by several fold** the amount in each [OxyADF/ACUROX] Tablet, **may cause a combination of unpleasant symptoms**. . . . When [OxyADF/ACUROX] Tablets are administered at the anticipated recommended maximum dose . . . it is intended that **legitimate pain patients will receive effective analgesic effects and not be aware of the potential effects of niacin.** However, when a person swallows excess quantities of [OxyADF/ACUROX] 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 . . . . [W]e anticipate that inclusion of niacin in [OxyADF/ACUROX] 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/ACUROX] 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/ACUROX] Tablets, and do not have the potential to cause these undesirable niacin effects.

[Emphasis Added.]

47. Likewise, specifically addressing the niacin in Acurox, the March 5, 2008, 10-K for 2007 stated:

> We believe that should a person swallow **excess quantities of Acurox™ Tablets** they will experience an unpleasant combination of symptoms. . . . . When Acurox™ Tablets are administered **at the anticipated recommended maximum dose** . . . it is intended that legitimate pain patients will receive effective analgesic effects **and not be aware of the potential dysphoric effects of niacin**. . . . [W]e anticipate that inclusion of niacin in Acurox™ Tablets and in other Aversion® Technology product candidates will **deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of Acurox™ Tablets.**

[Emphasis added.]

48. Finally, on April 30, 2008, Defendants filed Acura's 1Q:08 10-Q. Concerning Aversion Technology, the 10-Q stated that:

> We believe that **should a person swallow excess quantities of Acurox™ Tablets they will experience an unpleasant combination of symptoms** . . . . [N]iacin, when administered orally in immediate release tablets in amounts **exceeding by several fold** the amount in each Acurox™ Tablet, may cause a combination of unpleasant symptoms. In addition, it is generally recognized that niacin has a well established safety profile in long term administration at doses far exceeding the amounts in each Acurox™ Tablet. **When Acurox™ Tablets are administered at the anticipated recommended maximum dose . . . it is intended that legitimate pain patients will receive effective analgesic effects and not be aware of the potential dysphoric effects of niacin**. . . . [W]e anticipate that inclusion of niacin in Acurox™ Tablets and in other Aversion®

> Technology product candidates will deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of Acurox™ Tablets.

[Emphasis added].

49. These statements were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that niacin's negative "side effect profile" was experienced at **well** below the consumption of amounts exceeding by "ten-fold" or "several-fold" "the amount contained in the proposed maximum recommended daily dose" of Acurox. In truth, a huge percentage – up to 77% – of patients taking Acurox *at the recommended* dose experienced niacin's combination of negative side effects. Defendants already knew and/or recklessly disregarded, from their own clinical studies, and from knowledge in the medical community that existed even before the development of Acurox began, that they could not reasonably "expect[] that legitimate acute pain patients [would] not feel the affects [or be aware] of this extra active ingredient." Rather, niacin caused flushing effects.

50. Moreover, Defendants also knew and/or recklessly disregarded that when a person "consume[s] excess quantities of [Acurox]," any "unpleasant combination of symptoms" they experienced could be mitigated by taking aspirin or other NSAIDs, eating a high fat meal, or through the development of a tolerance to the side effects in just a matter of days. Furthermore, Defendants' studies showed that potential abusers of oxycodone did not significantly "dislike" the side effects of the niacin such that they would be deterred them from consuming or abusing the drug. Defendants thus knew and/or recklessly disregard that their representations that they anticipated that the "inclusion of niacin in [Acurox] 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 [Acurox] Tablets" were materially false and/or misleading.

Materially False and Misleading Statements and Omissions Regarding the Results of Acura's Clinical Studies of Acurox

51. The July 27, 2006, release announcing the Company's second quarter results also reported that Acura 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 [niacin] was determined to be well tolerated**" and that "**[n]o severe adverse events were reported in any treatment group . . ."**

52. In truth, but undisclosed to investors, Study 101 was a dose-finding study "to determine the appropriate strength of niacin to use in an Aversion technology formulation of oxycodone" in which Acura provided healthy volunteers with doses of niacin ranging from 0 to 75 mg. Through this study, Defendants determined that Acurox would contain 30 mg of niacin per tablet, or 60 mg per dose (patients would take two tablets with each dose). As noted in the FDA Briefing Materials of April 20, 2010, however, "Study 101 suggests that 60 mg of niacin would be expected to result in **an [sic] substantial incidence of vasodilatory complaints." "**Study 101 suggests that the **60 mg of niacin selected by the Applicant is too high."** Study 101 also showed that these effects—which were "too high" in the recommended dose, but were designed to dissuade drug abusers—were lessened simply by eating. As discussed above, Defendants also knew and/or recklessly disregarded that Study 103 not only confirmed the high incidence of negative side effects in normal users, but also showed that a tolerance to the side effects could be built up in just 10 days.

53. On March 15, 2007, Defendants 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 stated (for what appears to be the first time) that Acurox contained niacin. However, the March 15, 2007, release downplayed the importance of the disclosure that Acurox's second active ingredient was niacin 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." 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." In spite of the article's admission that "[i]n the fed state, the high fat meal eliminated the niacin induced disliking effect and delayed the time to peak blood level for oxycodone," it still reported that "[t]he 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. . . ."

54. In truth, according to the FDA's interpretation of the study, Study 102 showed that: "A fatty meal completely abolished the disliking effects of niacin in the combination drug" and furthermore, "the addition of niacin to 40 mg of oxycodone did not result in significant deterrent effects . . . , even under fasting conditions."

55. Concerning the status of the Company's clinical testing, the Company's 2007 10-K, filed March 5, 2008, expressly stated that only once **"Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile**, **Phase III trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites**."

56. However, at this time, Defendants already knew and/or recklessly disregarded that the Phase II clinical trials had demonstrated that the dosage range in Acurox was neither effective at dissuading abuse nor did it present an acceptable safety profile for non-abusers.

57. On April 24, 2008, Defendants issued a joint release with King Pharmaceuticals 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 Pharmaceutical'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 Pharmaceuticals then **"expect that ACUROX™ Tablets will be the first approved immediate-release opioid analgesic designed to resist or deter common methods of prescription drug abuse."** [Emphasis added.]

58. This statement was materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that they could not reasonably expect that Acurox would be approved, and, in addition, their clinical data already demonstrated that the drug was not adequately designed to resist or deter the most common method of prescription drug abuse—oral abuse.

59. 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 Acura

Chief Scientific Officer Spivey as stating:

> **The 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** . . . 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 . . . These 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. . . Acurox™ has 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.]

60. In truth, but undisclosed to investors, Defendants knew and/or recklessly disregarded that Study 105 was not an "important milestone" but was a flawed study that only further revealed Acurox's faults. Study 105 compared Acurox (which contains two active ingredients, oxycodone and niacin) to a placebo (which did not contain either active ingredient). Because the study failed to include a niacin-only or oxycodone-only arm, there was no way to distinguish which active ingredient caused the high instances of flushing experienced by patients taking the recommended doses of Acurox.

61. Moreover, Study 105 used niacin and oxycodone in two combinations: a dose with 60 mg of niacin and 10 mg of oxycodone; and a dose with 60 mg of niacin and 15 mg of oxycodone. The study showed that flushing did not increase with the higher dose of oxycodone, and even appeared to decrease, thus showing that oxycodone itself – like aspirin, other NSAIDs, or a high-fat meal – may have a negating effect on niacin's negative effects.

62. Finally, ketorolac, (an NSAID) was used as a "rescue medication" in Study 10. As a result, the FDA Joint Panel noted in its April 20, 2010, materials that "it is likely that the incidence of flushing in Study 105 was underestimated because of the high rate of ketorolac use."

63. On October 13, 2008, Acura and King Pharmaceuticals 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. These results are statistically significant based on the dislike/like scores** (p = .033), the primary measure of abuse deterrence potential for the study.

64. In truth, but undisclosed to investors, Defendants knew and/or recklessly disregarded that Study 111 showed *no statistically significant difference* in dislike/like scores between the Acurox containing the purportedly aversive niacin and the tablets containing oxycodone alone. In fact, Study 111 showed that oxycodone *reduced* the "dislike" produced by niacin. As the FDA Panel later concluded based on Study 111, "the aversive affects of niacin do not modulate the overall liking of oxycodone."

65. On October 27, 2008, Defendants filed Acura's 3Q:08 10-Q, which stated that the **"innovative Aversion® Technology platform has 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™ . . . has completed its pivotal Phase III clinical trial successfully meeting the primary pain relief endpoints**." 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 has ongoing additional clinical and non-clinical studies **intended to demonstrate the abuse deterrent features and benefits of Acurox™ Tablets**."

66. This statement was materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that Acura's Aversion Technology had not been "successfully utilized" but had been failing in clinical trials, even those that were poorly designed or structured to favor the technology and conceal its niacin component's negative effects.

67. 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:

> The 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.]

68. On March 2, 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, our lead product candidate, 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** . . . In addition, we believe . . . that niacin has a well established safety profile in long term administration at doses far exceeding the amounts in each product candidate utilizing Aversion® Technology. 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.]

69. These statements were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that their clinical studies had *not* shown "with statistical significance that subjects with a history of opioid abuse disliked Acurox compared to immediate release oxycodone HC1 alone when . . . swallowing excess numbers of tablets" nor had their studies determined Acurox to be "well tolerated when . . . administered at recommended doses." Rather, subjects with a history of opioid abuse did not sufficiently "dislike" Acurox, and could overcome any "dislike" by eating or taking aspirin, and other patients were experience negative side effects at recommended doses

70. 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 stated:

> **[The Company's] innovative Aversion® Technology platform has been successfully utilized in developing multiple opioid analgesic products candidates.** Development of Acurox® (oxycodone HCl/niacin) Tablets, our lead product candidate, **is supported by numerous laboratory studies and statistically significant and clinically meaningful Phase II and Phase III study results.** Additional product candidates in development are supported by laboratory and bioequivalence studies. Our portfolio of product candidates includes opioid analgesics intended to effectively relieve pain while simultaneously discouraging common methods of pharmaceutical product misuse and abuse. . . .

71. These statements were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that their Aversion Technology had not been "successfully utilized," nor had Defendants' studies produced "statistically significant [or]

clinically meaningful" results, rather, Defendants' studies had demonstrated that Acurox and its Aversion Technology were neither well tolerated nor effective.

72. On October 26, 2009, Defendants filed a Form 10-Q announcing the Company's 2Q:09 financial results. In the "Company Overview," Defendants again mentioned their "proprietary" Aversion Technology, "opioid analgesic product candidates [] intended to effectively relieve pain while simultaneously discouraging common methods of opioid product misuse and abuse," and "Acurox, [the Company's] lead product candidate." In addition, Defendants claimed that Acura and/or its licensee, King Pharmaceuticals, was developing several other opioid candidates utilizing Aversion Technology – *i.e.*, containing niacin – including "Vycavert® (hydrocodone bitartrate, niacin and acetaminophen), Acuracet® (oxycodone HCl, niacin and acetaminophen) and additional undisclosed opioid product candidates."

73. These statements were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that their clinical studies had shown that the niacin component of their Aversion Technology was neither well tolerated nor effective.

74. 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)**."

[Emphasis added.]

75. These statements were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded the following problems with Study 114, among others: Study 114 was submitted to the FDA after the Acurox and original clinical studies, and after the FDA had informed Defendants that Acurox would not likely be approved in its current form; some of the purported oxycodone abusers who were given oxycodone *alone* (not Acurox) in Study 114 reported that they would not use the drug again, a problem that later caused the FDA Joint Panel to question at the April 22, 2010, meeting whether the "wrong population" was studied, and whether, in light of the fact "some of the patients didn't actually want to use the oxycodone alone again," the drug trial patients were actually "drug abusers who abuse oxycodone at baseline"; Study 114 analyzed patients' "preference" between two different treatments, each with a different combination of niacin and oxycodone, and did not properly assess the aversive properties of Acurox of Acurox was all that was available to drug abusers (*i.e.*, while an oxycodone abuser might *prefer* the treatment that had 80 mg oxycodone and 0 mg of niacin over the treatment with 40 mg oxycodone and 240 mg niacin, the study did not assess whether the drug user would be dissuaded from using the 40 mg/240 mg combination if that was all that was available).

Materially False and Misleading Statements Regarding Acurox's Product Labeling and Commercialization

76. In Acura's March 15, 2007, Form 10-K for 2006; its May 4, 2007, 1Q:07, August 9, 2007, 2Q:07, and November 2, 2007, 3Q:07 Forms 10-Qs; its March 5, 2008, 10-K for 2007, and its April 30, 2008, Form 10-Q for 1Q:08, Defendants made materially false and misleading statements regarding their "Expectations" for Acurox's "Product Labeling." These filings, stated, in relevant part:

> [The Company is] seeking an indication for [OxyADF/AXUROX] Tablets for treatment of moderate to moderately severe pain. **The FDA has 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/AXUROX] Tablet product label. In this regard, the Company intends to seek FDA approval of language in the [OxyADF/AXUROX] 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/AXUROX] Tablets and other product candidates utilizing Aversion® Technology.

[Emphasis added.]

77. As to product labeling, and thus commercialization, the Company's October 27, 2008, 3Q:08 10-Q stated that "Acurox™ Tablets will 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 Defendants **"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 [Acura's] multiple laboratory and clinical studies designed to simulate the relative difficulty of abusing [the Company's] product candidates."** [Emphasis added.]

78. Concerning product licensing, and thus commercialization, the March 3, 2009, 10-K for 2008 and March 2, 2010, 10-K for 2009 also stated in relevant part that Defendants "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."

79. Accordingly, concerning "Expectations for Acurox Tablets Product Labeling,"

and thus commercialization, a March 3, 2009, release file by King and Acura 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.]

80. Not only was FDA approval of the drug crucial, but FDA approval of the language regarding abuse deterrence was also vital for Acurox to distinguish itself from dozens of other oxycodone-containing products on the market. However, Defendants' statements regarding the FDA's labeling guidance were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that Acura could not support Acurox's abuse deterrent qualities with "rigorous, scientific data." In truth, but undisclosed to investors, Acura's clinical studies, from the inception of the Class Period, had *already* demonstrated that Acurox did little to deter oral abuse and instead caused a negative side effect profiled in normal users. Defendants knew and/or recklessly disregarded that Acurox would not deter abusers from "swallow[ing] excessive numbers of tablets," and, as a result, Acura was unlikely to receive FDA approval for Acurox, unlikely to be permitted to label Acurox as an abuse deterrent, and unlikely to be able to "viabl[y] promot[e]" or "commercializ[e]" Acurox or other product candidates utilizing Aversion Technology.

Materially False and Misleading Statements Regarding Acura's Feedback from and Communications with the FDA

81. On June 23, 2009, Defendants filed a Form 8-K and issued a press release announcing their receipt of a June 18, 2009, "Preliminary Review Letter" regarding Acurox from the FDA. The article stated, in relevant part: "On February 22, 2009, Acurox was granted a priority review classification by the FDA with a Prescription Drug User Fee Act (PDUFA)

[decision] date of June 30, 2009." The article went on to reveal that, "[b]ased on this review letter, we do not believe Acurox Tablets will receive NDA approval on the PDUFA date." Defendants reassured investors, stating, the "FDA stated in the review letter that their comments are preliminary, subject to change, and do not reflect a final decision on the information reviewed or a review of the entire NDA."

82. Even on Defendants' minimal disclosure, Acurox stock fell. The value of Acurox stock dropped over 22% from a closing price of $7.57 on June 22, 2009, to close at $5.89 on June 23, 2009, on unusually high trading volume.

83. Moreover, Defendants' disclosure regarding the June 23, 2009, letter was materially incomplete. Around this same time, CW2 reports that Premier Research received a letter from the FDA that described Acurox as "toxic" in light of the high instance of adverse side effects experienced by patients at the recommended doses. CW2 also reported that the letter also questioned the efficacy of Acurox's oral abuse deterrent properties. Defendants thus knew and/or recklessly disregarded that there was little if any chance that the FDA would approve Acurox.

84. 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 raises 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 are currently evaluating the FDA's Complete Response Letter, **and at this stage believe they can respond to the issues raised without conducting any additional studies.** The Companies plan to meet with the FDA following submission of their response.

[Emphasis added.]

85. These same assurances were provided again in Acura's July 30, 2009, 2Q:09

financial release. The Company's 2Q:09 10-Q assured that "[t]he CRL raises issues regarding the potential abuse deterrent benefits of Acurox®. We are currently evaluating the CRL, and at this stage believe we can respond to the issues raised without conducting any additional studies. We plan to meet with the FDA following submission of our response to the CRL."

86. On August 6, 2009, Defendants issued a release assuring that "Acura . . . has 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 . . . are scheduled to meet with the FDA in late third quarter 2009 to discuss the CRL and the briefing package." [Emphasis added.]

87. Defendants' statements regarding the complete response letter were materially false and misleading when made because Defendants knew and/or recklessly disregarded that the letter was an indication that Acurox would **not be approved** and, as a basis for its denial, the FDA cited concerns regarding the occurrence of flushing in patients following exposure to the proposed recommended doses of Acurox, as well as the impact of food and NSAIDs on mitigating the disliking effects of niacin – factors which Defendants had known and/or recklessly disregarded were material concerns *throughout the entire Class Period.*

88. 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 investors that **"[t]he FDA indicated that no new clinical trials are required at this time."** [Emphasis added.]

89. 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®.**" [Emphasis added.]

90. The Company's 3Q:09 10-Q 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 are required at this time, [Acura] and King plan to initiate and complete an additional clinical study to further assess the abuse deterrent features of Acurox®**."

91. 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.]

92. Defendants capitalized on the opportunity to make the literally true statements that the FDA had not "required" any additional trials, while concealing and/or recklessly disregarding that they had ignored the FDA's recommendation to conduct additional studies, and that the clinical trials Acura had already conducted were faulty and poorly designed. Moreover, Defendants knew and/or recklessly disregarded that the studies the Company had conducted had actually demonstrated that Acurox was not an effective oral abuse deterrent and instead had a negative side effect profile at recommended doses. Moreover, Defendants knew and/or recklessly disregarded that they had failed to conduct a study regarding the impact of aspirin on the Company's Aversion Technology – a study specifically recommended by the FDA.

Materially False and Misleading Statements Regarding the Company's Code of Ethics

93. 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 to [Acura's] principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions." Acura's Code of Ethics, which was attached as an exhibit to the 8-K, expressly provided, in relevant part:

> The purpose of the Code is 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.]

94. Acura's Code of Ethics expressly provided that: "All 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 detailing "Accurate and Timely Periodic Reports" requirements, the Ethics Code stated:

> The Company is 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. The Company expects Designated Officers to establish and manage the Company's reporting systems and procedures with due care and diligence and for employees to cooperate with Designated Officers to ensure that:
>
> - **Reports filed with or submitted to the Securities and Exchange Commission and other public communications contain information that is full, fair, accurate, timely and understandable and do not misrepresent or omit material facts;**

[Emphasis added.]

95. Defendants' statements regarding Acura's Code of Ethics were materially false and misleading when made because Defendants knew and/or recklessly disregarded that Defendants had not complied, nor would they comply during the Class Period, with their Code of Ethics. Undisclosed to investors, Defendants did not take steps to "deter wrongdoing" or "promote" "[h]onest and ethical conduct" or "[f]ull, fair, accurate, timely, and understandable disclosure" in SEC filings and in fact, throughout the Class Period, Defendants had knowingly and/or with reckless disregard made a myriad of materially false and misleading statements

regarding the Company's lead product candidate and the success and viability of its key, propriety Aversion Technology.

THE TRUE FINANCIAL AND OPERATIONAL CONDITION OF ACURA IS BELATEDLY DISCLOSED

96. It was not until April 2010, more than a year after Defendants' first partial disclosure made on June 23, 2009, which resulted in a 22% decline in Acura shares, that the market began to learn additional information regarding Defendants' materially false and misleading statements and omissions regarding Acurox, an in particular, its efficacy, safety, marketability, and the likelihood that it would be approved by the FDA.

97. On April 20, 2010, the FDA posted on its website Briefing Materials for the April 22, 2010, joint meeting of the Anesthetic and Life Support Drugs and the Drug Safety and Risk Management Advisory Committees of the FDA. The FDA Briefing Materials stated what Defendants had known and/or recklessly disregarded throughout the Class Period: *that Acura's Aversion Technology was nowhere near effective enough to warrant approval*. For the first time, the market learned: the Company's clinical data was defective; its clinical studies were not properly designed; the Company had wholly ignored specific directives from the FDA over the past four years as to specific clinical trials that Acura should have conducted and evidence Acura should have provided; and Defendants had failed to present evidence to the FDA that niacin discouraged abusers from abusing oxycodone. Panelists also pointed out in the materials that Acura's own clinical data had demonstrated all along that any negative effects of niacin overdosing could be mitigated or eliminated simply by eating food or taking aspirin.

98. In contrast to Acura's claims that Acurox would not subject non-abusers to a side effect profile that was any different from taking oxycodone alone, the FDA's April 20, 2010, "Executive Summary" expressly disclosed that:

> While 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.

The FDA found that patients using Acurox in Acura's clinical trials, even at the recommended doses, were so prone to nausea and vomiting that they had to take other drugs to stop the symptoms. Specifically, the FDA found that only four patients on the placebo, compared to a whopping 135 patients on Acurox, had to take "antiemetics," drugs used to reduce nausea and vomiting. By comparison, patients taking regular, immediate release oxycodone demonstrated a far better side effect profile.

99. In addition, the FDA 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 cyclooxygenase inhibitor would likely blunt any vasodilatory reaction."

100. Concerning the debilitating effects on non-abusers, the FDA's Executive Summary also expressly disclosed that:

> Although 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.

101. Despite Defendants' repeated claims of abuse deterrence efficacy throughout the Class Period, the FDA's Executive Summary concluded:

> The 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.

102. 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**." [Emphasis added.] The FDA submitted an errata sheet clarifying that the Division had "suggested, but did not require, the applicant assess the effects of co-administration of aspirin," but the point remained the same: Defendants ignored the FDA's concerns.

103. 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.

104. As a result of this disclosure, Acura's stock price declined 25.3% in just two trading days, falling from a closing price of $7.90 on April 19, 2010, to close at $5.90 on April 20, 2010, on unusually high trading volume.

105. 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."

106. Critically, as reported by Reuters on April 22, 2010, following the 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.]

107. 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." The Bloomberg Article also noted that there had been "several delays" since just months after "Acura submitted a new drug application for Acurox with the FDA on Dec. 30, 2008" including the FDA's request for more information about the product's abuse-deterrent benefits six months after the NDA submission and "a [September 2, 2009] discussion with the agency in which King and Acura agreed to present their studies to an advisory panel."

108. As a result of these disclosures, Acura's stock price again declined on unusually high trading volume, falling over 31% from a closing price of $5.90 on April 21, 2010, to close at $4.02 on April 23, 2010. Acura stock continued to fall, later closing at $3.59 on April 28, 2010.

ADDITIONAL INDICIA OF SCIENTER

109. At the start of the Class Period, the Company's financial outlook was grim. In its 10-K filed on February 21, 2006, 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 it 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 a February 1, 2006 report, Acura's registered independent public accounting firm expressed **"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.]

110. Even after a January 2006 $750,000 bridge loan provided by a majority bloc of investors (the "Lead 2004 Investors"), "the Company had cash and cash equivalents of approximately $647,000" and Acura's cash reserves as of the 2005 10-K would only be "sufficient to fund the development of the Aversion® Technology and related operating expenses **only through mid-to-late March, 2006."** Furthermore, "The Company's future sources of revenue, if any, [would] 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.]

111. Defendants were motivated to issue false and misleading statements regarding the Company's potential for obtaining FDA approval because in doing so, Acura and its executives were able to secure, through a Securities Purchase Agreement with the Company's Lead 2004 Lenders, additional working capital for the Company in a period of strained financial circumstances, and to enter into a lucrative licensing agreement with King Pharmaceuticals Research and Development, Inc., a subsidiary of King Pharmaceuticals, Inc. (the "King License Agreement"). These financing arrangements in turn enabled Defendants to obtain listing on the NASDAQ Capital Market in February 2008 and become selected by Russell Investments in June 2008 for inclusion in the Russell 3000 Index, which measures the performance of the 3,000 largest U.S. companies, further inflating the value of Company stock.

112. On January 31, 2008, when Defendants disclosed that the Company's application to list its common stock on the NASDAQ Capital Market had been approved, Defendant Reddick noted that the listing "[would] provide enhanced liquidity and visibility and we are looking forward to attracting research analyst coverage as a result of our listing."

113. In return for these achievements, Defendants Reddick and Clemens were awarded substantial salary increases and bonuses.

114. In August 2007, Acura entered into a Securities Purchase Agreement with the Lead 2004 Investors (and others) to sell over 23.6 million "units" each comprising four shares and one warrant, in exchange for additional working capital, with expected net cash proceeds of approximately $14.5 million: and in October 2007, the Company registered 355,250,449 shares of the Company's common stock for resale by certain of its stockholders, including 345,649,572

shares owned by the Lead 2004 Investors.

115. Furthermore, as a result of reaching the King Licensing Agreement in December 2007, by which King provided financial arrangements advantageous to the Company in exchange for certain exclusive Acurox licensing and licensing options for Aversion Technology products, on December 10, 2007, Defendants announced that Acura had received a $30 million non-refundable cash payment from King, which the Company used in part to pay off a $5 million secured term note from the Lead 2004 Lenders. The Agreement also provided that Acura was entitled to receive additional cash payments from King of up to $28 million for Acurox Tablets and significant future payments and royalties should certain development and regulatory goals be met. Indeed, in June 2008, Acura received a $5 million milestone payment from King for "meeting the primary endpoint in its pivotal Phase III study," and in December 2008, Acura received a $3 million license option exercise fee from King for a product using the Aversion Technology.

116. Thus, based on Defendants' false and misleading claims that the Company's Aversion Technology was being successfully implemented, the Company was able to secure immediate working capital and every appearance of significant future financial gain, as well as listing on a prominent trading market and inclusion in exclusive market-tracking indexes.

117. These developments directly benefitted the Individual Defendants as well. As noted in a November 19, 2008, letter from Acura to the SEC—in response to questions regarding Acura's relationship with King—salary and bonus targets for Defendants Reddick and Clemens, and for Chief Scientific Officer Spivey, VP of Marketing and Administration James F. Emigh, and VP, Treasurer, and Corporate Controller Robert A. Seiser, included: completion of a private offering net proceeds of at least $10.0 million; repayment of the $5 million secured promissory

note from the Lead 2004 Lenders; and licensing of product candidates using Aversion® Technology to a pharmaceutical company partner. 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
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

118. According to the Company's 2005 10-K, for the Company's 2006 fiscal year the Employment Agreements with Defendants Reddick and Clemens provided for a cash bonus equal to 100% of their then-current base salaries "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)." According to the Company's 2008 annual proxy statement, Defendants Reddick 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 and Clemens received $1.375 million and $733,000 of stock awards while they readied the Company for the October 2007 King License Agreement.

ADDITIONAL ALLEGATIONS REGARDING THE INDIVIDUAL DEFENDANTS

119. Because of the Individual Defendants' positions with the Company, they each had access to the adverse undisclosed information about Acura's business, operations, products, operational trends, financial statements, markets, and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof, and *via* reports and other information provided to them in connection therewith.

120. As officers and controlling persons of a publicly-held company whose securities are registered with the SEC pursuant to the Exchange Act, publicly traded, and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

121. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public, shareholder, and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions there from, and were aware of their materially false and misleading nature. Because of their Board membership and/or executive and managerial positions with Acura, each

of the Individual Defendants had access to the adverse undisclosed information about Acura's business prospects and financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Acura and its business issued or adopted by the Company materially false and misleading.

122. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each of the Individual Defendants is responsible for the accuracy of the public reports and releases detailed herein and is therefore primarily liable for the representations contained therein.

123. Each of the Defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Acura securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme**:** (a) deceived the investing public regarding Acura's business, operations, management, and the intrinsic value of Acura securities; (b) enabled Defendants to artificially inflate the price of Acura shares; (c) caused Plaintiffs and other members of the Class to purchase Acura securities at artificially inflated prices.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

124. During the Class Period, the market for Acura's securities, including but not limited to common stock, was efficient for the following reasons, among others:

a. As a regulated issuer, Acura filed periodic public reports with the SEC and, as of February 4, 2008, with Nasdaq;

b. Throughout the Class Period, Acura was a publicly-traded stock registered with the SEC pursuant to Form S-3;

c. Acura regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

d. A significant volume of shares -- thousands of shares of Company stock -- traded each day of the Class Period;

e. Beginning February 4, 2008, Acura's stock was listed and actively traded on the Nasdaq national market exchange, a highly efficient and automated market; and

f. The share price of Acura securities reacted promptly to unexpected news events.

125. As a result of the foregoing, the market for Acura securities promptly digested current information regarding Acura from all publicly available sources and reflected such information in Acura stock price. Under these circumstances, all purchasers of Acura securities during the Class Period suffered similar injury through their purchase of Acura securities at artificially inflated prices and a presumption of reliance applies.

CAUSATION AND ECONOMIC LOSS

126. Defendants' publication of materially false and misleading statements during the Class Period had the intended effect of causing Acura's shares to trade at artificially inflated levels. As a result of Defendants' publication of these false statements, during the Class Period shares of the Company traded to a high of almost $25 per share in July 2007.

127. Contrary to the positive statements made by Defendants during the Class Period, however, through partial disclosures on June 23, 2009, April 20, 2010, and April 22, 2010, investors learned that the niacin component of the Company's purported "proprietary Aversion Technology" in its "lead product candidate" Acurox was neither effective, nor safe, and the drug

would not be approved by the FDA. These belated disclosures had an immediate, adverse impact on the price of Acura shares.

128. The declines in Acura's stock price after the disclosures on June 23, 2009, and April 20, 2010, and April 22, 2010, was a direct result of the nature and extent of Defendants' fraud and illegal course of conduct being revealed to investors and to the market over multiple disclosures. The timing and magnitude of Acura's stock price decline negates any inference that the losses suffered by Plaintiffs and the other members of the Class was caused by changed market conditions, macroeconomic or industry factors, or even Company-specific facts unrelated to Defendants' fraudulent conduct.

129. Moreover, during the same period in which Acura's share price fell dramatically as a result of Defendants' illegal and improper course of conduct and their fraud being revealed in June 2009 and April 2010 the Standard & Poor's 500 securities index was relatively unchanged. The economic loss, *i.e.*, damages suffered by Plaintiffs and other members of the Class, was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Acura's stock and the subsequent significant decline in the value of the Company's shares when Defendants' prior misstatements and other fraudulent conduct was revealed.

NO SAFE HARBOR

130. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded

herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Acura who knew that those statements were false when made.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

131. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the securities of Acura between February 21, 2006, and April 22, 2010, inclusive (the "Class") and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

132. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Acura common shares were actively traded on the OTC BB and on Nasdaq. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Acura or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

133. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of

federal law that is complained of herein.

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

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

i. whether the federal securities laws were violated by Defendants' acts as alleged herein;

ii. whether statements and or omissions by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Acura; and

iii. to what extent the members of the Class have sustained damages and the proper measure of damages.

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

COUNT I

Against Defendant Acura for Violation of Section 10(b) Of the Exchange Act and Rule 10b-5 Promulgated Thereunder

137. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

138. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing

public regarding Acura's business, operations, management and the intrinsic value of Acura securities; (b) enable Defendants to inflate and maintain the artificial inflation in the price of Company stock throughout the Class Period; and (c) cause Plaintiffs and other members of the Class to purchase Acura securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, jointly and individually (and each of them) took the actions set forth herein.

139. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Acura's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

140. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Acura as specified herein.

141. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Acura's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Acura and its business operations

and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Acura securities during the Class Period.

142. The Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts. Such Defendants' material misrepresentations and/or omissions were done knowingly or with reckless disregard for the purpose and effect of concealing Acura's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by recklessly refraining from taking those steps necessary to discover whether those statements were false or misleading.

143. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Acura securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Acura's publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Acura securities

during the Class Period at artificially high prices and were damaged thereby.

144. Plaintiffs 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. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Acura was experiencing, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Acura securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

145. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

146. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT II

Against the Individual Defendants for Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder

147. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

148. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public regarding Acura's business, operations, management and the intrinsic value of Acura securities; (b) enable Defendants to inflate and maintain the artificial inflation in the price of

Company securities throughout the Class Period; and (c) cause Plaintiffs and other members of the Class to purchase Acura securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, jointly and individually (and each of them) took the actions set forth herein.

149. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Acura's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

150. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Acura as specified herein.

151. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Acura's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Acura and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a

course of business which operated as a fraud and deceit upon the purchasers of Acura securities during the Class Period.

152. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (a) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (b) each of these Defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (c) each of these Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (d) each of these Defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

153. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts. Such Defendants' material misrepresentations and/or omissions were done knowingly or with reckless disregard for the purpose and effect of concealing Acura's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's products, business, operations and earnings throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by

recklessly refraining from taking those steps necessary to discover whether those statements were materially false or misleading when made.

154. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Acura securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Acura's publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Acura securities during the Class Period at artificially high prices and were damaged thereby.

155. Plaintiffs 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. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Acura was experiencing, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Acura securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

156. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

157. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and

the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT III

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

158. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

159. The Individual Defendants acted as controlling persons of Acura within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

160. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

161. As set forth above, Acura and the Individual Defendants each violated Section

10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

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

1. Determining that this action is a proper class action, certifying Lead Plaintiffs as Class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' Lead Counsel as Class Counsel pursuant to Rule 23(g);

2. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

3. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

4. Awarding extraordinary, equitable and/or injunctive relief as permitted by law, equity and the federal statutory provisions sued hereunder; and

5. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: March 14, 2011

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CERTIFICATE OF SERVICE

I hereby certify that on March 14, 2011, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses registered, as denoted on the attached Electronic Mail Notice List, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the Manual Notice List.

/s/ Matthew T. Heffner

MATTHEW T. HEFFNER