AMENDED CLASS ACTION COMPLAINT

Lead Plaintiff KB Partners I, L.P. ("KB"), individually and on behalf of all other persons similarly situated, by its undersigned attorneys, for its complaint against defendants, alleges the following based upon personal knowledge as to itself and its own acts, and information and belief as to all other matters, based upon, inter alia, the investigation conducted by and through its attorneys, which included, among other things, a review of the defendants’ public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Pain Therapeutics, Inc. (""PTIE"" or the "Company"), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.
NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than defendants who purchased PTIE securities between December 27, 2010 and June 26, 2011, inclusive (the "Class Period"), seeking to recover damages caused by defendants' violations of the federal securities laws and to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. PTIE describes itself as a "biopharmaceutical company," meaning that it tries to develop pharmaceutical products for commercial sale. Currently, however, it does not have any U.S. Food and Drug Administration ("FDA") approved drugs on the market. Its lead drug candidate is a painkiller called "REMOXY," a controlled-release oral capsule form of oxycodone that is formulated to reduce the risk of abuse and misuse of time-released oxycodone tablets currently on the market.

3. Pursuant to a Collaboration Agreement dated November 9, 2005 ("Collaboration Agreement"), PTIE worked with King Pharmaceuticals ("King") to submit REMOXY to the FDA for approval. PTIE and King submitted the first NDA for REMOXY in 2008, which the FDA rejected because the stability data provided in the chemistry, manufacturing, and controls ("CMC") section of the NDA did not demonstrate a consistent release of oxycodone over time. Thereafter, King took control of the resubmission process, focusing in particular on stability testing, and specifically provided Defendants Barbier and Friedmann, as well as other PTIE representatives, with periodic updates leading up to the second NDA resubmission in 2011. With no other drugs on the market, and their hopes resting on REMOXY, Defendants kept themselves fully informed regarding King’s testing methodologies and results during the resubmission process.
4. Following resubmission of the NDA (with new stability data) on December 27, 2010 (the beginning of the Class Period), Defendants made a series of misleading statements about REMOXY, which concealed the material facts, i.e., that: (1) King’s methodology for testing the stability of REMOXY, and in particular the time release mechanism, had been rejected as inappropriate and ineffective by PTIE years prior; (2) the results of King’s testing evidenced a lack of the requisite stability; and (3) approximately 25% of REMOXY tested in its first three months after manufacturing failed to meet the specifications for stability provided to the FDA. As a result, investors remained ignorant of a material risks regarding the approvability of REMOXY, which Defendants were duty bound to disclose.

5. While deceiving investors, Defendants padded their own wallets. Knowing that the FDA was scheduled to respond to the Company’s application for approval of REMOXY on June 23, 2011, and knowing there was a large risk of rejection, Defendants still granted a massive and unsubstantiated compensation package to the Company’s Chief Executive Officer, President and Chairman of the Board Remi Barbier. In the proxy filed on April 8, 2011, the Company recommended that shareholders approve a compensation package for Defendant Barbier of approximately $5.3 million for 2010, as compared to his 2009 compensation of approximately $1.6 million, a 331% increase. Not knowing about the stability issues that persisted in the retesting process, shareholders overwhelmingly approved this proposal.

6. On May 3, 2011, Pfizer (which had just acquired King) disclosed in a conference call with analysts that they were “working to address a specific issue in the manufacturing section of the [REMOXY] application” and that this manufacturing issue could “delay the timing of approval or the launch of Remoxy.” This partial revelation sent PTIE stock plummeting 7%.
7. Nevertheless, Defendants continued to mislead the Company’s investors. Mere days after Pfizer’s partial disclosure, Defendant Barbier presented at a Bank of America Merrill Lynch Health Care Conference during which he spoke about the FDA’s initial rejection of REMOXY, its request for additional “detailed stability work,” and the resubmission of the second NDA. Defendant Barbier failed, however, to disclose that the stability issues that doomed the first NDA remained unresolved in the second submission.

8. Thereafter, on June 24, 2011, the truth was partially revealed further when the Company announced that it had received a Complete Response Letter (“CRL”) from the FDA rejecting its second NDA for REMOXY. Defendants were not surprised but this news shocked investors and caused the stock price to decline by 43%.

9. Then, on June 27, 2011, the Company further disclosed that the FDA had rejected REMOXY because of “concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY.” Specifically, “Certain drug lots showed inconsistent release performance during in vitro testing.” Defendants knew about all these issues prior to the NDA submission but failed to tell investors despite the fact that these issues heightened the risk of FDA rejection. As a result of this additional revelation, PTIE shares declined an additional 26%.

10. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members suffered significant losses and damages.

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to 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.
12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

13. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). PTIE maintains its principal place of business in this District and many of the acts and practices complained of occurred in substantial part herein.

14. 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

15. Lead Plaintiff purchased PTIE securities at artificially inflated prices during the Class Period and was damaged thereby.

16. Defendant PTIE is a corporation organized under the laws of the state of Delaware, maintaining its principal place of business at 7801 N. Capital of Texas Highway, Suite 260, Austin, TX 78731.

17. Defendant Remi Barbier ("Barbier"), the Company’s founder, has served as PTIE’s President, Chief Executive Officer and Chairman of the Board of Directors since the Company’s inception in 1998.

18. Defendant Nadav Friedmann ("Friedmann") has served as PTIE’s Chief Operating Officer since 2001 and Chief Medical Officer since October 2004 and has served as a director since September 1998.

19. Defendant Peter S. Roddy ("Roddy") has served as PTIE’s Chief Financial Officer since November 2002.
20. The defendants referenced above in ¶¶ 17 - 19 are referred to herein as the “Individual Defendants.”

SUBSTANTIVE ALLEGATIONS

BACKGROUND

21. PTIE is a biopharmaceutical company which researches and develops novel drugs. PTIE, however, has never had a drug approved by the FDA. Its lead drug candidate is called REMOXY (controlled-release oxycodone). REMOXY is a strong painkiller with a unique formulation designed to reduce potential risks of abuse. REMOXY is being developed pursuant to a strategic alliance with King Pharmaceutical, Inc. (“King”). In February 2011, Pfizer acquired King.

22. PTIE and King jointly managed a Phase III clinical program for REMOXY beginning in December 2004. They announced positive results in September 2005. In December 2007, Defendants announced that the Phase III clinical trial for REMOXY had met its primary endpoints. Thereafter, in mid-2008, PTIE and King submitted the first NDA for REMOXY. Following the FDA’s rejection of the first NDA in December 2008, King took control of the submission process for the second REMOXY NDA, as detailed infra.

23. The economic terms of PTIE and King’s alliance were outlined in all of the Company’s SEC filings, including a press release the Company filed on February 3, 2011 announcing its financial results for the year ended December 31, 2010. The Company stated the following, in relevant part:

REMOXY Related Milestone Payments and Royalty

- To date, we have received from King total cash payments of $185.0 million in program fees and milestone payments in connection with the development of REMOXY and other abuse-resistant drug candidates. We are eligible to receive up to $120.0 million in additional
clinical/regulatory milestone payments, including a $15 million payment upon FDA approval of REMOXY.
• Upon the commercial launch of REMOXY, we will receive from Pfizer a running royalty equal to 20% of net sales in the U.S., except as to the first $1.0 billion in cumulative net sales, which royalty is set at 15%. Outside the U.S., the royalty rate is set at 10%.
• In addition, we will also receive from Pfizer a supplemental royalty fee payment of 6 to 11.5% of net sales, depending on the range of total dollar sales in each year. This supplemental payment is equal to the full amount of our financial obligations to Durect Corporation (Nasdaq:DRRX), our exclusive supplier of certain excipients in REMOXY.

The FDA’s Rules Regarding the CMC

24. The FDA requires rigorous scientific testing to ensure that a drug is safe and effective for its intended use before the Agency will permit it to be marketed in the United States. Before considering approval of a drug for its indicated use, the Agency requires a “sponsor” to submit an NDA for consideration, which contains data from clinical trials, preclinical studies, and manufacturing information that supports the product’s safety and efficacy.

25. According to 21 CFR 314.50(d)(1), the CMC section of a NDA includes the following:

(1) Chemistry, manufacturing, and controls section. A section describing the composition, manufacture, and specification of the drug substance and the drug product, including the following:

(i) Drug substance. A full description of the drug substance including its physical and chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability, sterility, particle size, and crystalline form. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative sources, process controls, and analytical
procedures. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may satisfy relevant requirements in this paragraph.

(ii)(a) Drug product. A list of all components used in the manufacture of the drug product (regardless of whether they appear in the drug product) and a statement of the composition of the drug product; the specifications for each component; the name and address of each manufacturer of the drug product; a description of the manufacturing and packaging procedures and in-process controls for the drug product; the specifications necessary to ensure the identity, strength, quality, purity, potency, and bioavailability of the drug product, including, for example, tests, analytical procedures, and acceptance criteria relating to sterility, dissolution rate, container closure systems; and stability data with proposed expiration dating. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative components, manufacturing and packaging procedures, in-process controls, and analytical procedures. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may satisfy relevant requirements in this paragraph.

(b) Unless provided by paragraph (d)(1)(ii)(a) of this section, for each batch of the drug product used to conduct a bioavailability or bioequivalence study described in §320.38 or §320.63 of this chapter or used to conduct a primary stability study: The batch production record; the specification for each component and for the drug product; the names and addresses of the sources of the active and noncompendial inactive components and of the container and closure system for the drug product; the name and address of each contract facility involved in the manufacture, processing, packaging, or testing of the drug product and identification of the operation performed by each contract facility; and the results of any test performed on the components used in the manufacture of the drug product as required by §211.84(d) of this chapter and on the drug product as required by §211.165 of this chapter.

(c) The proposed or actual master production record, including a description of the equipment, to be used for the manufacture of a commercial lot of the drug product or a comparably detailed description of the production process for a representative batch of the drug product.

(Emphasis added.)

26. The statute is clear that a company must include detailed stability data in the CMC section of its NDA. Indeed, according to the FDA’s website, the purpose of stability studies at the NDA stage is:
To establish appropriate retest or expiration dating period applicable to all future drug substance and drug product batches manufactured, packaged and stored under similar circumstances

To establish the long-term storage conditions

To provide evidence of the effect of various environmental conditions on the quality of the drug substance and drug product

The FDA’s First Denial of REMOXY

27. In mid-2008, PTIE submitted its first NDA for REMOXY, which the FDA accepted with priority review. In December 2008, PTIE received a Complete Response Letter from the FDA rejecting the REMOXY NDA as non-approvable. It did so due to the lack of adequate stability data.

28. In a subsequent press release, Defendants told PTIE shareholders that the FDA requested additional “non-clinical” data on REMOXY. They provided no additional details regarding the nature of the “non-clinical” data requested but assured investors that “the FDA has not requested or recommended additional clinical efficacy studies prior to approval.”

29. In 2009, King assumed sole responsibility for the regulatory approval of REMOXY. In light of this development, and the resulting fact that PTIE’s non-executive employees now had nothing to do, Defendants promptly fired nearly 80% of its employees. Pursuant to the Collaboration Agreement, King was required to, and did, update PTIE at least quarterly throughout the stability retesting and NDA resubmission process. Thus, the three Individual Defendants -- by virtue of their key positions at PTIE, the fact that PTIE now had less than ten employees, and that fact that REMOXY was the Company’s lifeblood -- were fully aware of all
aspects of the REMOXY resubmission process including the methodology King was utilizing and the results of the stability testing it was performing.

30. Indeed, with no other source of income, PTIE depended on King’s REMOXY-related milestone payments for all of its revenue.

31. Between the FDA’s 2008 rejection of REMOXY and the filing of the second NDA in 2011, despite awareness of the deficiencies in the prior stability data, Defendants remained cryptic regarding the exact reasons for the first denial, leaving investors to guess as to the stumbling blocks that prevented REMOXY’s initial approval.

32. On July 7, 2009, the Company issued a press release entitled, “King and Pain Therapeutics Announce REMOXY(r) NDA Update.” That release provided investors with their only hint regarding the reasons for the FDA’s 2008 rejection of REMOXY. It stated in relevant part:

King Pharmaceuticals, Inc. (NYSE:KG) and Pain Therapeutics, Inc. (Nasdaq:PTIE) today announced that on July 2, 2009, King met with the U.S. Food and Drug Administration (FDA) to discuss the Complete Response Letter regarding the New Drug Application (NDA) for REMOXY(r). The outcome of this meeting provided King with a clear path forward to resubmit the REMOXY(r) NDA and to address all FDA comments in the Complete Response Letter.

King now anticipates the resubmission of the NDA could occur mid-year 2010. The Company believes the rate-limiting step is the generation of six-month stability data, and no new clinical trials are required. King remains committed to the development and commercialization of REMOXY(r), and looks forward to working closely with the FDA toward approval of the product.

(Emphasis added).

Stability Issues Remain Unresolved In the Second NDA

33. Defendants knew that stability testing on the REMOXY drug lots had not yielded consistent results during the retesting process. In accordance with the Collaboration Agreement, King kept PTIE fully apprised of its chosen methodologies for testing REMOXY’s stability and
the results of that testing. Indeed, PTIE and King disagreed vehemently regarding the proper methodology to employ to test stability of REMOXY due to the drug’s challenging consistency. However, Defendants failed to disclose material facts to investors, i.e., that: (1) King’s methodology for testing the stability of REMOXY, and in particular the time release mechanism, had been rejected as inappropriate and ineffective by PTIE years prior; (2) the results of King’s testing evidenced a lack of the requisite stability in the time release mechanism of the drug; and (3) approximately 25% of REMOXY tested in its first three months after manufacturing did not meet the specifications for stability provided to the FDA. As a result, investors remained ignorant of material risks regarding the approvability of REMOXY which defendants were duty bound to disclose.

34. Confidential Witness 1 (“CW1”), worked at PTIE from December 2000 until August 2011 as Senior Director of Information Technology in the company’s San Mateo, California headquarters office. According to CW1, as of October 2010, PTIE had only eight employees. CW1 maintained a close relationship with PTIE’s Vice President of Technical Operations, Mike Zamloot (“Zamloot”) in 2010. Zamloot often vented to CW1 regarding the REMOXY resubmission process.

35. According to CW1, Zamloot believed that King was headed down the wrong path in attempting to demonstrate REMOXY’s stability. The methodologies that King employed to test REMOXY’s stability were methods that PTIE had ruled out years prior. The company had to take samples of product every few months to make sure that the drug remained within the specifications set forth in its NDA. In 2010, Zamloot told CW1 that 25% of the REMOXY product tested within the first three months did not meet the stability specifications provided to the FDA. King realized, however, that if it began the stability testing timeline at the three-month
mark, the stability of REMOXY improved significantly. Therefore, King asked the FDA if it could have a 90-day “curing period” before conducting stability testing; i.e. if it could wait until the three month mark before beginning its stability testing. As CW1 learned from Zamloot, the FDA told King that these stability results indicated to the FDA that King had no control over the manufacturing process for REMOXY.

36. Statements made by other Confidential Witnesses support the foregoing. Confidential Witness 2 (“CW2”) was the Director of Strategic Sourcing at PTIE’s San Mateo, California headquarters office. He worked for PTIE for approximately eleven years until his termination in mid-2009. CW2 reported directly to Zamloot.

37. According to CW2, PTIE had developed an “erosion theory” to test the stability and effectiveness of REMOXY because it’s high viscosity liquid formulation made it impossible to use traditional methodologies for testing stability. CW2 indicated that there are acceptable methodologies for testing stability of a drug product. For example, one can take a drug tablet, put it in a glass cylinder, fill that cylinder with fluid, and then take samples at intervals of time to evaluate how much of the drug was released out of the tablet. REMOXY, however, is a high viscosity liquid formulation that doesn’t represent the traditional physical characteristics of a tablet. CW2 compared it to chapstick or honey, which change dramatically when you rub them or introduce heat. The physical nature of REMOXY presented a challenge in terms of testing the stability and effectiveness because typical tablet methodologies did not work. According to CW2, PTIE developed an “erosion theory” to demonstrate REMOXY’s stability and effectiveness to the FDA. PTIE told King that the erosion theory worked and could convince the FDA of REMOXY’s stability. However, King would not accept PTIE’s erosion methodology. In
fact, as PTIE well knew, King ignored PTIE’s stability data completely when it took over the NDA resubmission process.

38. Confidential Witness 3 (“CW3”) was the executive assistant to Defendants Barbier and Friedmann from 1999 until September 2011. According to CW3, Barbier and Friedman were the PTIE employees that received the updates from King’s CEO Brian Markenson, and then Pfizer, pursuant to the Collaboration Agreement throughout the resubmission process.

39. Confidential Witness 4 (“CW4”) was a Director of Formulations and Pharmaceutical Development at King and then Pfizer from 2003 until December 2011. In that role he planned, performed, directed, and managed the development and manufacture of pharmaceutical dosage forms intended for experimental use, clinical trials, and market through Phase 3 internally and through contract pharmaceutical organizations. CW4 also acted as CMC Team Leader for two acquired high-profile abuse deterrent products.

40. CW4 stated that the issues with the second NDA submission were the same as those that caused the FDA’s first non-approval. According to CW4, those issues concerned “dissolution and viscosity,” which related to the drug’s stability over increments of time. CW4’s superiors at King had frequent conversations with the top executives at PTIE (i.e. Defendants Barbier, Friedmann, and Roddy) about this issue throughout the retesting process.

41. In addition, CW4 stated that after King took over the process for the resubmission of the NDA for REMOXY, it conducted extensive background research to discern the problems with the first submission. However, PTIE kept pressuring King to expedite the process because of timing of the financial agreements between PTIE and King. According to CW4, PTIE threatened to sue King if it did not expedite its submission. PTIE needed money and wanted King to pay.
42. Confidential Witness 5 ("CW5") was a Senior Vice President of Pharmaceutical & Preclinical Research and Development at Pfizer (which had acquired King) from January 2010 through December 2011. In that role, CW5 managed CMC, discovery and preclinical activities. CW5 reported to the Chief Science Officer.

43. CW5 confirmed that, with regard to the second NDA submission, Defendants were aware there were problems, but were hoping the FDA would overlook them.

44. Confidential Witness 6 ("CW6") was Director of Finance at PTIE from 2000 until September 2011. According to CW6, the FDA denied the second REMOXY NDA for two reasons: 1) King had not figured out a new way to test the drug’s stability in relation to how the body digests REMOXY, i.e. the excipients were not proven stable; and 2) King could not demonstrate an adequate shelf life for REMOXY. CW6 further stated that Defendants Barbier and Friedmann, Zamloot, and Mike Marsman, the Director of Regulatory Affairs, met with King representatives to discuss the REMOXY resubmission process. CW6 confirmed that Defendant Barbier drafted all of the Company’s Class Period press releases after the Company downsized the Manager of Investor Relations in 2009 following REMOXY’s first FDA rejection.

45. Confidential Witness 7 ("CW7") was a Vice President of Pharmaceutical Development at King and then Pfizer from 1992 until November 2011. CW7 reported to CW5. CW7 confirmed that King/Pfizer had a legal obligation to keep PTIE apprised of the status of any work done on REMOXY or the NDA no less than quarterly. CW7 confirmed that the top executives at PTIE were the only ones who participated in meetings with the top executives at King, and later Pfizer, regarding the REMOXY retesting and resubmission process.
MATERIALLY MISLEADING
CLASS PERIOD STATEMENTS

46. Throughout the Class Period, Defendants issued misleading statements indicating that the stability issues, which they had identified as the “rate limiting step” causing the first FDA rejection, had been resolved. Specifically, Defendants told investors that they had responded to the FDA’s 2008 denial letter in the resubmitted NDA even though the stability issues raised in that letter persisted. In addition, throughout the Class Period, Defendants described the FDA’s initial rejection of REMOXY, the request for additional non-clinical data, and the resubmission, but failed to disclose the ongoing stability problems or explain what the Company was doing to address those problems.

47. On December 27, 2010, the Company issued a press release, drafted by Defendant Barbier, announcing that King had resubmitted the NDA for REMOXY to the FDA in response to the December 2008 CRL:

King Pharmaceuticals®, Inc. (NYSE:KG) and Pain Therapeutics®, Inc. (Nasdaq:PTIE) today announced that King has resubmitted a New Drug Application (NDA) for REMOXY® (oxycodone) to the U.S. Food and Drug Administration (FDA) in response to a Complete Response letter received by Pain Therapeutics in December 2008. This is a Class 2 resubmission with a six month review cycle.

(Emphasis added.) Defendants thoroughly reviewed the NDA, including the CMC section, prior to submission. The NDA confirmed that King had not utilized PTIE’s “erosion” methodology but instead utilized a methodology that Defendants believed could not demonstrate the stability of a drug with REMOXY’s unique consistency, and that the data failed to demonstrate the requisite stability of the drug.

48. On February 3, 2011, when the Company filed an annual report for the year ended December 31, 2010 on Form 10-K (“2010 10-K”) with the SEC, which was signed by Defendants Barbier, Roddy and Friedmann. The 10-K provided in relevant part:
We and King jointly managed a Phase III clinical program and NDA submission for REMOXY. In mid-2008, the FDA accepted our NDA for REMOXY with Priority Review. In December 2008, we received from the FDA a Complete Response Letter for the NDA for REMOXY. In this Complete Response Letter, the FDA indicated additional non-clinical data is required to support the approval of REMOXY. The FDA has not requested or recommended additional clinical efficacy studies prior to approval. In 2009, King assumed sole responsibility for the regulatory approval of REMOXY. This shift of responsibility did not change any economic term of our strategic alliance with King. In December 2010, we and King announced that King had resubmitted the REMOXY NDA. In January 2011, we announced that the FDA had accepted King’s resubmission of the REMOXY NDA.

49. On April 6, 2011, Defendant Roddy spoke about REMOXY at the tenth annual Needham & Company Healthcare Conference. At the conference, Defendant Roddy once again presented a misleadingly incomplete picture of the REMOXY resubmission process by failing to disclose the enduring stability issues. In addition, Defendant Roddy implied his full knowledge of the stability testing process and indicated those issues had in fact been resolved in the second NDA. Specifically, Defendant Roddy stated:

In June 2008 we filed the NDA for REMOXY. And at that time we received a $15 million milestone payment in connection with the FDA's acceptance of the NDA. That August, the FDA granted the NDA priority review. We participated in FDA Advisory Panel meeting in November 2008 and in the end, the Advisory Panel voted in favor of REMOXY.

Then we received the complete response from the FDA in December 2008. Again, no new clinical efficacy trials were required for approval, and no change to the formulation was required as well. But in particular, the FDA asked for additional stability data on REMOXY's novel formulation. That and other information was submitted to the FDA in December. Again the resubmission accepted in January of this year.

50. On April 27, 2011, the Company filed a quarterly report for the period ended March 31, 2011 on Form 10-Q with the SEC, which was signed by Defendants Barbier and Roddy. The 10-Q represented the following concerning REMOXY:

We and King jointly managed a Phase III clinical program and NDA submission for REMOXY. In mid-2008, the FDA accepted our NDA for REMOXY with
Priority Review. In December 2008, we received from the FDA a Complete Response Letter for the NDA for REMOXY. In this Complete Response Letter, the FDA indicated additional non-clinical data was required to support the approval of REMOXY. The FDA has not requested or recommended additional clinical efficacy studies prior to approval. In 2009, King assumed sole responsibility for the regulatory approval of REMOXY. This shift of responsibility did not change any economic term of the King Agreements. In December 2010, King resubmitted the REMOXY NDA. In January 2011, we announced that the FDA had accepted the resubmission of the REMOXY NDA.

51. The statements referenced in ¶¶ 47 - 50 above were misleading because they failed to disclose material facts, i.e. that: (1) King’s methodology for testing the stability of REMOXY’s time release mechanism over time had been rejected as inappropriate and ineffective by PTIE years prior; (2) the results of King’s stability testing evidenced a lack of the requisite stability in the time release mechanism of the drug; and (3) approximately 25% of REMOXY tested in its first three months after manufacturing did not meet the specifications for stability provided to the FDA. As a result, investors remained ignorant of material risks regarding the approvability of REMOXY which defendants were duty bound to disclose.

THE TRUTH IS PARTIALLY REVEALED, BUT DEFENDANTS CONTINUE TO MAKE MISLEADING STATEMENTS

52. On May 3, 2011, in a conference call with analysts, Pfizer disclosed the following concerning REMOXY:

At this time we’re working to address a specific issue in the manufacturing section of the application as well as to understand any potential implications for FDA’s recent-class-wide [Risk Evaluation and Mitigation Strategy] announcement for extended release opioids.1 These issues could delay the timing of approval or the launch of Remoxy.

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1 In 2009, the FDA sent letters to various manufacturers indicating that certain opioid products would be required to have a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that benefits outweigh risks.
This partial disclosure did not reveal that the “specific issue in the manufacturing section” related to stability testing, the same “rate-limiting” issue that prevented FDA approval in 2008.

53. As a result of this partial disclosure, PTIE shares declined $0.70 per share or more than 7%, to close at $8.86 per share on May 3, 2011. Had investors learned the full truth, the decline would have been much larger.

54. On May 11, 2011, Defendant Barbier presented at a Bank of America Merrill Lynch Health Care Conference. At that conference, Defendant Barbier stated the following, in relevant part:

The NDA was originally filed in June of 2008. We received a complete response letter in December of that year, we ha[d] to go back to some more work as is often the case with these things.

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The regulatory history; again the original NDA was filed in June 2008. We received from the FDA priority review and we're granted priority review almost immediately. We had FDA advisory panel in November of 2008 during, which 11 were in favor of approving REMOXY versus eight that were against. Why were the eight against? I don't know. It's almost like there is always someone against Christmas, I suppose.

We did receive a complete response from the FDA in December of 2008. It wasn't the right answer, but it was an answer. Particularly they confirm that no new clinical efficacy work is necessary. But they did ask us for more detailed stability work, which was done in the interim between 2008 and 2010. NDA w[as] resubmitted with the PDUFA date of June 23rd of this year.

55. Later in the conference, when speaking about Pfizer’s May 3 partial revelation, Defendant Barbier continued to hide the persisting stability issues with REMOXY and said the following:

So what does it mean? First of all, I'm not the oracle for Pfizer. I'm not a spokesperson for Pfizer; they are a company, we are a company. So if there is a secret meaning in these words, I don't have it. But I've heard a lot of conspiracy theories behind this. I actually subscribe, I take this exactly as it is.

First of all, I think it is extraordinary that the CEO of Pfizer during an earnings call would come up and talk about REMOXY, keep in mind this is a drug that five years ago people were still doubting whether it was a legitimate drug and
whether there was room for REMOXY. Suddenly fast forward to today, you've got the CEO arguably, one of the biggest pharmaceutical companies guiding on REMOXY. We like that, in fact, I think it is extraordinarily positive signal.

Furthermore in the Q&A session, I believe the CEO of Pfizer did affirm that it is not if REMOXY gets approved, but when REMOXY gets approved, again an affirmative action or sentence on the of REMOXY.

56. During that same conference, in response to analyst Gregory Fraser’s question about Defendant Barbier’s insight into the FDA review process, Barbier confirmed that Pfizer was obligated to, and did, keep him fully informed.

57. On June 24, 2011, the Company shocked investors by announcing that a Complete Response Letter was received from the FDA regarding the resubmission of the NDA for REMOXY whereby the FDA rejected the drug for a second time. Without disclosing the contents of the Complete Response Letter, the Company merely disclosed that “Pfizer is working to evaluate the issues described in the Complete Response Letter and plans to have further discussions with FDA around them.”

58. As a result of this revelation, PTIE shares declined $3.94 per share or nearly 43%, to close at $5.30 per share on June 24, 2011.

59. On June 27, 2011, the Company provided further detail regarding the FDA’s letter. In a press release, the Company disclosed the following:

Based on its review, the FDA has determined that the NDA for REMOXY is not approved.

The FDA’s Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. Certain drug lots showed inconsistent release performance during in vitro testing. It is not known at this time whether this is an artifact of the testing method or a manufacturing deficiency.

Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the FDA’s Complete Response Letter. In the opinion of Pain Therapeutics, potential regulatory approval of REMOXY in the
U.S. is unlikely to occur in less than one year, and could be delayed significantly longer than a year.

(Emphasis added).

60. As a result of this revelation, PTIE shares declined an additional $1.37 per share or nearly 26%, to close at $3.93 per share on June 27, 2011.

61. On June 28, 2011, Bart Classen (“Classen”), an analyst at Summer Street Research Partners published an analyst report stating the following:

Manufacturing is a much more likely cause of the problem and will likely require at least a year to correct. Testing manufacturing lots does not need to be done for submission of the NDA but is required before launch. It is likely the lots were not tested before the 2008 FDA review. Our consultant believes there could be variability in the narcotic binding to the sugar matrix of Remoxy. The binding is likely to be highly sensitive to humidity and pressure. A small change could affect the binding and later, the release of the narcotic. It could take well over a year to fix. Pouring of the product into the capsule could also be the cause of the problem. This could require the purchase of custom-built pouring machines. This problem could also take more than a year to correct.

62. The materiality of the stability data deficiencies is further evidenced by the fact that, to date, Pfizer has not resubmitted the NDA for REMOXY nor has it updated investors regarding any plan to do so. Defendants have also failed to provide investors with any meaningful update on the plans for, or likelihood of, another resubmission of the REMOXY NDA.

63. PTIE’s share price never recovered. On June 4, 2012, PTIE stock closed at $3.66 a share.

ADDITIONAL SCIENTER ALLEGATIONS

57. Defendants’ knowledge or reckless disregard of the deficient stability data is evidenced by the fact that,

(a) The REMOXY NDA was initially rejected because of time release stability data problems;
(b) As three of its less than ten remaining employees, and as members of PTIE’s core management, Defendants Barbier, Friedmann, and Roddy knew that the Company’s financial future was dependent upon getting REMOXY resubmitted and approved;

(c) Pursuant to the Collaboration Agreement, King had an obligation to keep PTIE apprised regarding the retesting and resubmission process;

(d) Defendants Barbier and Friedmann were the two PTIE executives who received these periodic updates on the REMOXY retesting/resubmission process from King, and later Pfizer.

(e) Defendants knew that approval was dependent on developing a methodology for effectively testing the stability of REMOXY’s time release mechanism;

(f) Defendants knew that the stability testing methodology King used could not demonstrate REMOXY’s stability;

(g) Defendants’ skepticism was borne out by the results of the retesting performed by King, which continued to fail to demonstrate the requisite stability in the data submitted to the FDA at the outset of the Class Period;

(h) Defendants knew, or recklessly disregarded, that the resubmitted NDA showed the stability data deficiencies generated by King’s use of a faulty methodology;

(i) Despite such knowledge, company management rewarded themselves with unjustifiable compensation packages. Specifically, in the proxy filed on April 8, 2011, the Company recommended that shareholders approve a compensation package for Defendant Barbier of approximately $5.3 million for 2010, as compared to his 2009 compensation of approximately $1.6, a 331% increase. Defendants knew that if they had
waited until after the FDA rejected REMOXY they would have had a difficult time justifying such lavish compensation

64. CW1 indicated that Defendant Barbier had “a history of lying,” both internally to employees and publicly. CW6 also described Defendant Barbier as a person who "hides a lot of stuff."

**PLAINTIFF’S CLASS ACTION ALLEGATIONS**

65. Plaintiff brings 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 PTIE securities during the Class Period (the “Class”); and were damaged thereby. Excluded from the Class are defendants herein, 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.

66. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, PTIE securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes 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 PTIE 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.
67. Plaintiff’s 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.

68. Plaintiff 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. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

69. 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:

- whether the federal securities laws were violated by defendants’ acts as alleged herein;
- whether statements made by defendants to the investing public during the Class Period were misleading;
- whether defendants acted knowingly or recklessly in issuing misleading statements;
- whether the prices of PTIE securities during the Class Period were artificially inflated because of the defendants’ conduct complained of herein; and
- whether the members of the Class sustained damages and, if so, what is the proper measure of damages.

70. 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.
71. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- PTIE securities are traded in efficient markets;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased and/or sold PTIE securities between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

72. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

**COUNT I**

(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)

73. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

74. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

75. During the Class Period, defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the
other members of the Class; omitted to state material facts necessary in order to make the statements identified here, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of PTIE securities; and (iii) cause Plaintiff and other members of the Class to purchase PTIE securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

76. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for PTIE securities and options. Such reports, filings, releases and statements were materially misleading in that they failed to disclose material adverse information and misrepresented the truth about the risks of a second FDA rejection of REMOXY.

77. By virtue of their positions at PTIE, defendants had actual knowledge of the materially misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed
willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

78. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of PTIE. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disclose material facts about the problematic stability data which rendered FDA approval of REMOXY uncertain.

79. As a result of the dissemination of the aforementioned misleading reports, releases and public statements, the market price of PTIE securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning PTIE’s business and financial condition which were concealed by defendants, Plaintiff and the other members of the Class purchased PTIE securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by defendants, and were damaged thereby.

80. During the Class Period, PTIE securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased shares of PTIE securities at prices artificially inflated by defendants’ wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased said securities or would not have purchased them at the inflated prices that were paid. At the time of the purchases by Plaintiff and the Class, the true value of PTIE securities were substantially lower than the prices paid by Plaintiff and the
other members of the Class. The market price of PTIE securities declined sharply upon public
disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

81. By reason of the conduct alleged herein, defendants knowingly or recklessly,
directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5
promulgated thereunder.

82. As a direct and proximate result of defendants’ wrongful conduct, Plaintiff 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, upon the disclosure that the
Company had been disseminating misleading statements to the investing public related to its
prospects for FDA approval.

**COUNT II**

(Violations of Section 20(a) of the
Exchange Act Against The Individual Defendants)

83. Plaintiff repeats and realleges each and every allegation contained in the
foregoing paragraphs as if fully set forth herein.

84. During the Class Period, the Individual Defendants participated in the operation
and management of PTIE, and conducted and participated, directly and indirectly, in the conduct
of PTIE’s business affairs. Because of their senior positions, they knew the adverse non-public
information regarding a specific risk of non-approval of PTIE’s NDA submission to the FDA.

85. Because of their positions of control and authority as senior officers, the
Individual Defendants were able to, and did, control the contents of the various reports, press
releases and public filings which PTIE disseminated in the marketplace during the Class Period
concerning PTIE’s financial prospects. Throughout the Class Period, the Individual Defendants
exercised their power and authority to cause PTIE to engage in the wrongful acts complained of
herein. The Individual Defendants therefore, were “controlling persons” of PTIE within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of PTIE securities.

86. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by PTIE.

**PRAYER FOR RELIEF**

WHEREFORE, Lead Plaintiff demands judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Lead Plaintiff as the Class representative;

B. Requiring defendants to pay damages sustained by Lead Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Lead Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys’ fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

**DEMAND FOR TRIAL BY JURY**

Lead Plaintiff hereby demands a trial by jury.

Dated: October 15, 2012

Respectfully submitted,

POMERANTZ GROSSMAN HUFFORD DAHLSTROM & GROSS LLP

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