



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 develops drugs utilizing proprietary technology. The Company develops safer or more efficacious drugs for use in pain management, particularly in the area of opioid painkillers.

3. Throughout the Class Period, Defendants conditioned investors to believe that FDA approval of REMOXY would be forthcoming through a host of materially false and misleading statements regarding the status of REMOXY’s ongoing clinical studies. Specifically, Defendants failed to disclose that REMOXY was not approvable by the U.S. Food and Drug Administration (“FDA”) due to chemistry, manufacturing, and control deficiencies that caused inconsistent results during laboratory tests of REMOXY. As a result of the foregoing, the Company’s statements were materially false and misleading at all relevant times.

4. On June 24, 2011, the Company announced that it had received a Complete Response Letter from the FDA which did not approve the New Drug Application (“NDA”) for REMOXY and as a result, PTIE’s partner, Pfizer Inc. (“Pfizer”) was evaluating the issues described in the Complete Response Letter.

5. 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.

6. On June 27, 2011, the Company disclosed that the FDA’s Complete Response Letter raised concerns related to, among other things, the chemistry, manufacturing, and controls sections of the NDA for REMOXY. Specifically, certain drug lots in the NDA submission showed inconsistent release performance during *in vitro* testing.

7. 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.

8. 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 have suffered significant losses and damages.

### **JURISDICTION AND VENUE**

9. 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.

10. 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.

11. 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.

12. 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**

13. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased PTIE securities at artificially inflated prices during the Class Period and was damaged thereby.

14. 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.

15. 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.

16. 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.

17. Defendant Grant L. Schoenhard (“Schoenhard”) has served as PTIE’s Chief Scientific Officer since 2001.

18. Defendant Peter S. Roddy (“Roddy”) has served as PTIE’s Chief Financial Officer since November 2002.

19. The defendants referenced above in ¶¶15 - 18 are referred to herein as the “Individual Defendants.”

## **SUBSTANTIVE ALLEGATIONS**

### **BACKGROUND**

20. PTIE is a biopharmaceutical company which engages in the research and development of novel drugs. PTIE’s lead drug candidate is called REMOXY (controlled-release oxycodone). REMOXY is a strong painkiller with a unique formulation designed to reduce potential risks of unintended use. REMOXY and other abuse-resistant painkillers are being developed pursuant to a strategic alliance with King Pharmaceutical, Inc. (“King”). In February 2011, Pfizer acquired King. PTIE and King jointly managed a Phase III clinical program and NDA submission for REMOXY.

21. In mid-2008, the FDA accepted the Company's NDA for REMOXY with Priority Review. In December 2008, PTIE received from the FDA a Complete Response Letter for the NDA for REMOXY. In the Complete Response Letter, the FDA requested additional non-clinical data on REMOXY. In 2009, King assumed sole responsibility for the regulatory approval of REMOXY. This shift of responsibility did not change any economic term of the Company's strategic alliance with King.

22. On December 27, 2010, the Company announced that King had resubmitted a NDA for REMOXY to the FDA in response to the December 2008's Complete Response letter. On January 27, 2011, the Company announced that the FDA had accepted the NDA resubmission for REMOXY and has classified it as a Class 2 resubmission, giving a corresponding Prescription Drug User Fee Act ("PDUFA") goal date of June 23, 2011.

**MATERIALLY FALSE AND MISLEADING  
STATEMENTS MADE DURING THE CLASS PERIOD**

23. On February 3, 2011, in a press release, the Company announced 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.

24. On February 3, 2011, the Company filed an annual report for the year ended December 31, 2010 on Form 10-K with the SEC, which was signed by Defendants Barbier, Roddy and Friedmann representing the Company's financial results and financial position. In addition, pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), the Form 10-K contained signed certifications by Defendants Barbier and Roddy, stating that the financial information contained in the Form 10-K was accurate, and that they disclosed any material changes to the Company's internal control over financial reporting.

25. On April 25, 2011, the Company announced in a press release top-line results of an abuse liability study with REMOXY where it "met all prospectively defined primary endpoints." The full study results were published in Pain Medicine and were presented at the American Pain Society Annual Scientific Meeting on May 19-21, 2011. The press release stated the following, in relevant part:

***"The Abuse Potential of Remoxy, an Extended-Release Formulation of Oxycodone, Compared with Immediate and Extended-Release Oxycodone", (Pain Medicine 2011; vol 12(4);618-631)***

#### **Study Objective**

The study was designed to evaluate the abuse potential of REMOXY relative to oxycodone extended-release (ER), oxycodone immediate release (IR) and placebo.

#### **Study Design**

This was a double blind, placebo and active-controlled, six-way crossover study. The study enrolled 45 healthy adult volunteers with histories of non-dependent recreational opioid use, defined as having recreationally abused opioids to achieve a euphoric high on at least five occasions in the previous 12 months, and at least once in the 90 days before screening visits. The study assessed the abuse potential of Remoxy 40 mg whole and chewed, oxycodone ER 40 mg whole and crushed, oxycodone IR 40 mg crushed and placebo. Treatments were

administered in-clinic under various fed/fast conditions that produced the highest bioavailability for each drug (i.e., REMOXY in the fed state and oxycodone in the fasted state).

### Study Results

The primary endpoint was Drug Liking, as assessed by various pharmacodynamic parameters. Thirty-two subjects were included in the endpoint analyses. In this study:

- Drug Liking was significantly lower ( $p < 0.05$ ) for REMOXY 40mg (whole) compared with oxycodone ER 40mg (whole) or oxycodone IR 40 mg.
- Drug Liking was significantly lower ( $p < 0.05$ ) for REMOXY 40mg (chewed) compared with oxycodone ER 40mg (crushed) or oxycodone IR 40 mg.

Time to Peak Drug Liking was significantly delayed ( $p < 0.05$ ) for REMOXY 40mg (chewed) compared with oxycodone ER 40mg (crushed) or oxycodone IR.

Secondary endpoints included Drug High and Good Effects, chewing duration, taste/texture assessments and safety assessments. These secondary endpoints generally demonstrated the same consistency of effects observed in the primary endpoints.

In addition, no subject could chew REMOXY for more than 1.5 minutes (mean = 48 seconds) despite an allotted time of 10 minutes, due to the unpleasant taste/texture of REMOXY.

26. On April 27, 2011, the Company reported financial results for the first quarter ended March 31, 2011. The Company stated the following, in relevant part:

Pain Therapeutics believes that its flagship drug candidate, REMOXY<sup>®</sup>, can generate meaningful revenue after its commercial launch by Pfizer, Inc. (NYSE:PFE) based on the sheer size of the market, Pfizer's marketing heft and strong presence in pain management, the potential advantages of REMOXY over existing products and the Company's 15-20% royalty on net sales in the U.S.

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Our lead drug candidate, REMOXY, is a twice daily, long-acting formulation of oral oxycodone for moderate to severe pain requiring continuous, around-the-clock opioid treatment for an extended period of time. We developed this drug candidate to help address the growing problem of non-medical use of prescription opioids. REMOXY is designed to provide steady, around-the-clock pain relief,

while resisting common methods of tampering intended to result in the rapid release of oxycodone.

27. 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 representing the Company's quarterly financial results and financial position. In addition, pursuant to SOX, the Form 10-Q contained signed certifications by Defendants Barbier and Roddy, stating that the financial information contained in the Form 10-Q was accurate, and that they disclosed any material changes to the Company's internal control over financial reporting.

28. In addition, the 10-Q represented the following concerning REMOXY:

In April 2011, we announced top-line results of an abuse liability study with REMOXY and that the article entitled "The Abuse Potential of REMOXY, an Extended-Release Formulation of Oxycodone, Compared with Immediate- and Extended-Release Oxycodone" was published in Pain Medicine, the Official Journal of the American Academy of Pain Medicine. In the study, REMOXY met all prospectively defined primary endpoints.

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We will receive a \$15.0 million cash milestone payment from King upon regulatory approval of REMOXY in the United States. We could also receive up to \$105.0 million in additional milestone payments in the course of clinical development of the other abuse-resistant opioid painkillers. Subject to certain limitations, King is also obligated to fund development expenses incurred by us pursuant to the King Agreements, which result in collaboration revenue. King is obligated to fund the commercialization expenses of, and has the exclusive right to market and sell, drugs developed in connection with the King Agreements. The royalty rate for net sales of REMOXY and the other three abuse-resistant product candidates covered by the King Agreements in the United States is 20%, except as to the first \$1.0 billion in cumulative net sales in the United States, for which the royalty is set at 15%. The royalty rate for net sales of products covered by the King Agreements outside the United States is 10% on all of net sales.

29. The statements referenced in ¶¶ 23-28 above were materially false and/or misleading because they misrepresented and failed to disclose that REMOXY was not approvable by the FDA due to chemistry, manufacturing, and control deficiencies that caused inconsistent results during laboratory tests of batches of REMOXY.

**THE TRUTH IS REVEALED**

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

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. These issues could delay the timing of approval or the launch of Remoxy.

31. As a result, PTIE shares declined \$0.70 per share or more than 7%, to close at \$8.86 per share on May 3, 2011.

32. On June 24, 2011, the Company announced that a Complete Response Letter was received from the FDA regarding the resubmission of the NDA for REMOXY whereby the FDA delayed approval of 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."

33. 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.

34. 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.

35. 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.

36. 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.

#### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

37. 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.

38. 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.

39. 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.

40. 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.

41. 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 misrepresented material facts about the business, operations and management of PTIE;
- whether the Individual Defendants caused PTIE to issue false and misleading financial statements during the Class Period;
- whether defendants acted knowingly or recklessly in issuing false and misleading financial 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 have sustained damages and, if so, what is the proper measure of damages.

42. 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.

43. 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.

44. 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)**

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

46. 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.

47. 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; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; 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.

48. 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 false and misleading in that they failed to disclose material adverse information and misrepresented the truth about PTIE's finances and business prospects.

49. By virtue of their positions at PTIE, defendants had actual knowledge of the materially false and 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 false and 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.

50. Defendants were personally motivated to make false statements and omit material information necessary to make the statements not misleading in order to personally benefit from the sale of PTIE securities from their personal portfolios.

51. Information showing that defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of PTIE, the Individual Defendants had knowledge of the details of PTIE internal affairs.

52. 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-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to PTIE's businesses,

operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and 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.

53. 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 false and 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.

54. 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.

55. 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 misrepresented financial 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)**

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

57. 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 PTIE's NDA submission to the FDA.

58. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to PTIE's financial condition and results of operations, and to correct promptly any public statements issued by PTIE which had become materially false or misleading.

59. 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.

60. Each of the Individual Defendants, therefore, acted as a controlling person of PTIE. By reason of their senior management positions and/or being directors of PTIE, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, PTIE to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of PTIE and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

61. 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**, 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 Plaintiff as the Class representative;

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

C. Awarding 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**

Plaintiff hereby demands a trial by jury.

Dated: December 2, 2011